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PRINCIPAL INVESTIGATOR: Suzanne M. Miller, Ph.D.

CONTRACTING ORGANIZATION: Fox Chase Cancer Center
Philadelphia, Pennsylvania 19111

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Suzanne M. Miller, Ph.D.

E-Mail: Suzanne.Miller@fccc.edu

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14. ABSTRACT
The Behavioral Center of Excellence (BCE) in Breast Cancer was established to provide a comprehensive, multidisciplinary approach for studying the process of, and methods for facilitating, successful adaptation in the context of breast cancer risk, treatment, and recovery. The four ongoing studies are derived from and integrated by a unifying theoretical framework, and ere supported by four care facilities (i . e . , Administrative, Communication, Genetic Testing and Bioinformatics Core). The four projects are: 1) development of an intervention to promote utilization of breast cancer risk assessment programs and adherence to screening recommendations and underserved African-American women; 21 use of a "teachable moments and tailored communication materials to g r a t e utilization of risk assessment and adherence to screening amen0 daughters of diagnosed breast cancer patients 3) the g r m t i o n of psychological and physical adaptation among breast cancer patients at the completion of active treatments., during the re-entry phase); 4) promotion of psychological adaptation among metastatic breast cancer patients. The overarching goal is to develop theoretically guided, tailored, and transportable breast cancer communications to enhance screening adherence, decision-making, and quality of life across the spectrum of disease (i . e . , from risk through treatment to survivorship).

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DOD Progress Report, Project I
Understanding Breast Cancer Risk Assessment and Screening Behaviors Among the Underserved

Suzanne M. Miller, Ph.D., Principal Investigator
Joanne S. Buzaglo, Ph.D., Co-Investigator
Andrea Barsevick, D.N.Sc., R.N., AOCN, Co-Investigator

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

Breast cancer represents a serious health issue for African American women. Higher morbidity and mortality rates in this population may be due, in part, to lower uptake of breast cancer risk assessment and genetic counseling programs, as well as lower adherence to breast cancer screening recommendations (Miller & Champion, 1997). Yet, little information currently exists with respect to the psychosocial factors that facilitate participation in, and adherence to, available breast cancer risk assessment and screening programs. Further, there are no established intervention protocols to address the needs of this population. Guided by the research team's Cognitive-Social Health Information-Processing (C-SHIP) model, the overarching goal of Project 1 is to identify and assess barriers and facilitators to participation in breast cancer risk assessment and to adherence to breast cancer screening recommendations among African American women (Miller, 1995; Miller, 1996; Miller, Shoda, & Hurley, 1996; Miller, Fang, et al., 1999). These data will be used to develop and pilot test an intervention program to boost enrollment in breast cancer risk assessment programs and increase adherence to breast cancer screening guidelines among African American women.

The specific aims for Project 1 are as follows:

Aim 1: To develop a psychosocial assessment instrument, tailored to low-income African American FDRs of breast cancer patients, which assesses key psychosocial predictors of breast cancer surveillance behaviors (*Phase 1*).

Aim 2: To evaluate the psychometric nature of this questionnaire and to identify key longitudinal predictors (e.g., fatalism, attentional style) of participation in breast cancer risk assessment and of adherence to breast cancer screening recommendations (*Phase 2*).

Aim 3: To examine the feasibility and short-term impact of a cognitive-social intervention that is designed from Phase 1 and 2 data (*Phase 3*). Feasibility variables include number of recruitment calls needed, recruitment and attrition rates, level of satisfaction with the intervention, and degree to which women would recommend the program to others. Impact variables will include intention to pursue breast cancer risk assessment programs and adherence to breast cancer screening guidelines.

In Phase 1, we will conduct focus groups with African American FDRs of breast cancer patients ($N = 30$) to develop a psychosocial assessment of barriers and facilitators of participation in risk assessment programs and adherence to screening guidelines. We expect that low monitoring as well as a pattern characterized by low levels of knowledge about genetic risk and assessment programs, inaccurate risk perceptions, high fatalistic beliefs, low pros and high cons about risk assessment, and extremely high levels of emotional distress will emerge as important correlates of program interest and screening adherence. Phase 2 will be a longitudinal study with African American FDRs of breast cancer patients ($N = 100$) to evaluate the psychometric nature of this instrument and to identify prospective psychosocial predictors of intention/readiness to pursue breast cancer risk assessment and screening adherence. We hypothesize that high monitoring, as well as greater knowledge, higher risk perceptions, lower fatalism, higher pros and lower cons, and moderate levels of emotional distress will predict greater readiness to pursue risk assessment

and higher levels of screening adherence. In Phase 3, we will examine the feasibility and impact of an intervention for African American FDRs of breast cancer patients (N = 30) on interest in breast cancer risk assessment and screening adherence. We hypothesize that 75% of FDRs approached will agree to participate and that there will be a 20% attrition rate. Further, FDRs receiving this intervention will demonstrate greater interest in risk assessment program, as well as greater screening adherence.

Study findings will have applicability to enhancing current cancer prevention and control initiatives with underserved populations. This study will: 1) provide a theory-guided instrument for identifying women less likely to pursue risk assessment and adhere with screening guidelines; 2) identify a feasible, evidence-based approach to motivating breast cancer screening and participation in risk assessment programs among traditionally underserved women; and 3) provide information concerning the need for the simultaneous targeting and tailoring of interventions to promote decision-making about breast cancer assessment and adherence to surveillance behaviors. Overall, this study will provide important data for implementing breast cancer health-promotion interventions among underserved women on a broader scale.

BODY

The goal was to accomplish Task 1 and initiate Task 2 as outlined in our Statement of Work. Task 1 involved refining a psychosocial familial risk questionnaire, tailored to low-income African American FDRs of breast cancer patients, that assesses key psychosocial correlates of interest in breast cancer risk assessment programs and adherence to breast cancer screening guidelines (*Phase 1*). We subdivided this task into the following sub-tasks:

a. Submit Protocol to Institutional Review Boards
b. Recruit Focus Group Participants for Phase 1
c. Conduct Focus Groups
d. Analyze Focus Group Data
e. Develop Assessment Instrument for Phase 2

Task 2 involved evaluating the psychometric nature of the psychosocial familial risk questionnaire and identifying key longitudinal predictors of participation in breast cancer risk assessment and of adherence to breast cancer screening recommendations among female African American FDRs of breast cancer patients (N = 100; *Phase 2*). We subdivided this task into the following sub-tasks:

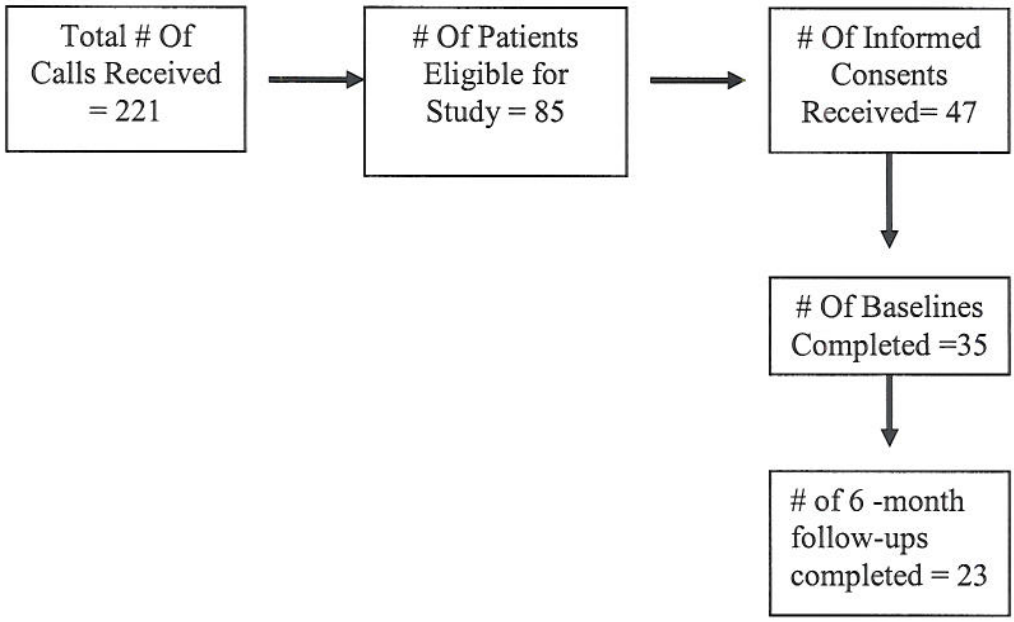
a. Submit Protocol to Institutional Review Boards
b. Establish Recruitment Procedures/Staff Training for Phase 2
c. Recruit Participants, Conduct Longitudinal Study

To date, we have completed *Phase 1* of the overall project (i.e., Task 1, a-e). We have also submitted the protocol for *Phase 2* to the FCCC IRB for review and received approval (i.e., task 2, a) and began *Phase 2* data collection in the spring of 2004. Recruitment for this Phase of the project is ongoing. We are currently using flyers as the primary means by which to invite participants to participate in the project. Four new sites have agreed to receive our flyers and

strategically place them at meetings and gatherings where their members are most likely to congregate, in order to assist in our recruitment efforts. The sites include two religious organizations (Christ Baptist Church, The Women of Faith and Hope Organization) one breast cancer heath information seminar (Sisters for the Cure Health Program), and one breast cancer center that facilitates mentorship between breast cancer survivors and the newly diagnosed (Delaware Breast Cancer Coalition). The FCCC IRB has approved these amendments. Once the DOD IRB has approved the relevant amendments, the flyers will be distributed to these organizations. The goal now is to continue subject recruitment and participation for Task 2. As of September, 2005 Dr. Robert Schnoll is no longer at FCCC and Dr. Joanne Buzaglo has assumed his responsibilities on the project.

Below, in Figure 1, we summarize our recruitment status for phase 2 of this project.

Figure 1: Summary of Recruitment Efforts (phase 2)



We have accrued 47 participants to date. Participants (only the 35 participants who completed the baseline included) characteristics include:

Average age = 48
Median age = 41

Education:
High School = 7
Some College = 17
Bachelor's Degree = 3
Graduate Degree = 8

We have devised a number of innovative recruitment strategies. As mentioned above, we plan to use flyers as to invite participants to participate in the project. Four new sites have agreed to receive our flyers and strategically place them at meetings and gatherings where their members are most likely to congregate, in order to assist in our recruitment efforts.

As part of Phase1, we conducted focus groups with African American First-Degree Relatives (FDRs) of breast cancer patients (N = 27). Data from these focus groups have been used to develop a psychosocial assessment of barriers and facilitators of participation in risk assessment programs and adherence to screening guidelines. Further, guided by the Cognitive-Social Health Information Processing (C-SHIP) model, we are applying a qualitative approach to explore patterns of cognitive-affective profiles of African-American and their attitudes and beliefs about breast cancer risk and the options available to them. These qualitative data have been transcribed and will be scored and analyzed to delineate and describe the individual's risk-related responses, in terms of their patterns of: risk perceptions, outcome efficacy of risk assessment procedures, risk-related distress, values related to the uptake of prevention and screening behaviors, and self-regulatory strategies to cope with the challenges associated with hereditary risk. These qualitative data will be used to enrich our understanding of the quantitative dataset by specifying more clearly the content of at-risk individuals' concerns. This is a unique data set in that it combines qualitative and quantitative approaches to the understanding and analysis of how minority women process complex information related to hereditary risk to breast and ovarian cancer, and the decisions and behaviors that ensue over time.

KEY RESEARCH ACCOMPLISHMENTS OF PHASE TWO

- Attend and participate in monthly Center meetings.
- The total number of participants currently enrolled in the study is 47; out of which 35 completed baseline assessment and 23 completed the 6-month follow-up intervention.
- The Leadership Core applied for and received DOD approval for a no-cost one-year extension.
- Submitted an amendment to Fox Chase Cancer Center Institutional Review Board requesting approval to add four new recruitment sites that was approved in October 2006. Currently waiting for approval from the DOD IRB.

REPORTABLE OUTCOMES

None

CONCLUSION

Overall, we have successfully completed Phase 1 of this project, namely the focus group interviews with 27 participants. Phase 2 recruitment of this project will continue. Four additional sites have agreed to allow us to recruit additional participants through the use of flyers. Upon approval from the DOD IRB, we will provide the additional sites with flyers and continue our recruitment efforts. We expect that we will achieve our recruitment goals with this uniquely challenging, and understudied population and successfully complete the study through additional recruitment efforts.

REFERENCES

N/A

DOD Progress Report, Project II
A Teachable Moment within the Family: From Concept to Community

Mary B. Daly, MD, Principal Investigator
Dr. Suzanne M. Miller, Ph.D., Co-Investigator
Samuel Litwin, Ph.D., Statistician

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

Despite advances in cancer detection and treatment, breast cancer remains the most common cancer among women and accounts for a staggering number of lives lost per year. Knowledge about both the genetic and environmental causes of breast cancer is being translated into tailored screening protocols, chemoprevention approaches, and diet and lifestyle modifications, targeted to women at highest risk. First-degree relatives (FDRs) of breast cancer patients comprise a particularly appropriate group among whom to concentrate efforts to maximize risk reduction and early detection. Although a family history of breast cancer is a well-known risk factor, studies have shown that many women are unsure of their risk status and are often unaware of the cancer prevention strategies that may be appropriate for them. The diagnosis of breast cancer in a close relative may provide the ideal opportunity, a "teachable moment," to reach at-risk family members to address their needs and concerns and make available risk assessment and counseling programs. The goals of the proposed study are to test a health communication message personalized to a set of demographic, clinical and psychosocial factors and timed to capitalize on the heightened awareness of breast cancer risk attendant to the recent diagnosis in an FDR. The project represents a partnership between a comprehensive cancer center (FCCC) and a series of community hospitals (FCCC Network affiliated sites) in an effort to enhance dissemination of state-of-the-art cancer prevention and control strategies to the community setting. Affected patients identify at-risk relatives at each site, and permission is sought to contact them by phone for participation in the study. Study participants are randomized to either a personalized message keyed to age, risk level, family history, screening behaviors and attention style, or to a general, non-personalized health message. Surveys are administered to adult daughters and sisters at two time points -- baseline and 12 months later -- in order to capture both newly formed intentions to seek cancer risk information and counseling, adopt lifestyle changes, and/or initiate appropriate surveillance regimens, and the actual action upon these intentions. The C-SHIP model of cognitive-affective processing of health threats is used as the theoretical framework for this study.

Aim 1: To develop and evaluate a theory-driven message tailored to a set of relevant variables including monitoring attentional style to enhance participation in FCCC's Family Risk Assessment Program (FRAP). The hypotheses are that patients exposed to this tailored message will be more likely to 1) seek risk assessment and counseling through FRAP, and 2) adopt risk-reducing behaviors than those patients who receive a non-tailored risk message.

Aim 2: To examine the moderating effects of individual differences in educational level, relationship to the patient, and level of anxiety and cancer-related distress.

BODY

The focus in the project during the past year has been continued recruitment of participants at FCCC and VirtuaHealth. In order to increase the pool of potential participants, a protocol amendment was approved to change the inclusion criteria to sisters and daughters of women newly diagnosed with breast cancer within the last three to twelve months (previously we

defined "newly diagnosed" as six to twelve months from date of diagnosis). The last year has also focused on ongoing capture of data, as well as some interim data analysis.

The study staff at FCCC continued work with the coordinator at VirtuaHealth to explore viable recruitment strategies. We met with the physicians and staff at the two local medical practices with the greatest potential to identify and refer appropriate patients for the study. The protocol amendment was also approved at this site. The other two network sites, Reading and Paoli, terminated the protocol due to lack of accrual. This was a function of staffing constraints at each site as well as limited staff ability to identify breast cancer patients in the local medical practices.

During Year 5, with Task 1-subtasks a and b completed, we continued with the following sub-tasks:

c. Finalization of recruitment strategies
d. Training of study personnel

Sub-task c.-Finalization of recruitment strategies, is an ongoing, dynamic process as we continue to explore viable strategies at both FCCC and the network site. We have continued to display study brochures and flyers at various locations throughout FCCC and in physicians' offices in the Virtua community. Additionally, study staff has participated in various community events to recruit participants. Brochures are displayed and staff members are available to answer questions about the study. The Project Coordinator continues working with the network site to try and establish viable recruiting strategies in the face of very limited human resources at the site.

Sub-task d.- The Project Coordinator communicates with the study team on an ongoing basis to identify problems, develop support tools and streamline the scheduling and implementation of the counseling sessions. The list of frequently asked questions (FAQs) and answers continues to be updated with input from the counselors evolving during their sessions with study participants.

We continued working on Task 2, Conducting a prospective, randomized trial. This task was subdivided into sub-tasks that are being completed on an ongoing basis.

a. Identification of FDRs
b. Mailing of pre-call letter
c. Baseline telephone interview
d. Follow-up letter
e. Delivery of experimental and control sessions
f. Quality control tests performed on a randomized sample of sessions
g. Follow up print materials mailed to participants
h. Informatics Core to complete data entry and management
i. Conduct 12-month follow up phone call

Patients are continuously identified through our clinical information system using the new 3-12 month inclusion criteria. Once eligible patients are identified, the study staff contacts them to set up a time to meet when they are scheduled to be at FCCC for a routine appointment. Once we briefly introduce the study to the patient over the phone and assess preliminary interest and

eligibility, a time and place to meet in person is arranged. A member of the study staff then meets with the patient, explains the study, obtains informed consent and assists the patient in completing the Relative Information form (RIF) to identify their eligible FDRs **(subtask a)**. In several cases this year, FDRs have contacted the study staff directly as a result of obtaining a brochure while accompanying their relative to a clinic appointment. This minimizes the need to recruit the patient and complete the RIF first, streamlining the process of recruiting the FDR directly. As of September 1, 2006 identification of breast cancer patients and their FDRs was discontinued to allow for FDR's completion of the study during the final year of the grant.

Once the RIF is completed, precall letters are then mailed to the FDR **(subtask b)** along with the Relative Informed Consent and HIPAA forms to introduce the study. If the FDR does not call to decline participation within a specified timeframe, the Informatics Core generates a contact log. This log flags the date for a member of the study staff to follow up on the precall letter with a phone call to assess the FDRs interest in participating in the study. Once we assess eligibility and the FDR has agreed to participate, the study staff obtains informed consent from the participant and asks her to sign and return the informed consent and HIPAA authorization forms.

Another phone call is scheduled for the baseline telephone interview **(subtask c)** at which time the baseline HHQ is completed over the telephone. The survey takes between 20-45 minutes to complete. The variability in time is mostly due to the size of the family and the accompanying family history information being collected. This call only takes place once the signed forms are received back by the study staff. A photocopy of the signed consent and HIPAA forms are then sent to the FDR for their records. Another call is scheduled within a few weeks of the baseline interview for the delivery of the counseling session.

Once the interview is completed, a follow up letter **(subtask d)** is generated by the Informatics Core and provided to the study staff. This letter confirms the date and time for the upcoming telephone counseling session and is sent along with a small monetary reimbursement to the participant thanking her for her time and interest in participating. The baseline HHQs are entered into the database and the participant is randomized to either the experimental or control groups. A tailored script is generated for each woman in the experimental group based on several variables captured during the baseline telephone interview. An algorithm was developed with the Informatics Core to create the script for each participant in the tailored group. These variables include attention style, family history/risk level and compliance with breast cancer screening. For women in the control group, a general health information script is generated covering such topics as diet, dietary supplements and exercise. The Project Coordinator reviews each script to ensure that the tailoring algorithm is correctly applied to the script and that the text is personalized for the specific participant.

The experimental and control counseling sessions **(subtask e)** are completed by two Health Educators trained to administer the intervention. The sessions take from 10-30 minutes and conclude with a description of the local Family Risk Assessment Program with contact information on how to enroll. Participants are given an opportunity to ask questions throughout the session and are given additional resources (e.g. NCI website, Cancer Information Service) by the counselor as appropriate to the individual situation.

Four counseling sessions was audiotaped with permission from the participant and the Project Coordinator reviewed these tapes to assess quality control of sessions **(subtask f)**. Sessions are being delivered appropriately and the format of the scripts encourages interaction between the participant and the counselor. The counselor notes participants' comments throughout the session and completes an evaluation form at the end of each session. The Project Coordinator reviews all evaluation forms and addresses any problems or questions that arose during the session.

Follow up print materials (i.e. fact sheets) are then mailed to participants **(subtask g)** within two weeks after the completion of the counseling sessions. These materials were developed with the Communications Core to correspond to the tailoring variables utilized in the tailored intervention group. Additionally, a fact sheet was created to reinforce information disseminated to control group participants. Also included in this mailing is a brochure and invitation to enroll in FRAP for more in-depth counseling and education about their risk for developing breast cancer.

The Informatics Core staff enters and manages the data **(subtask h)** on an ongoing basis. Study staff continues to meet with the Informatics Core on a regular basis to ensure that participant data are being captured and project timelines are being met. Several project management reports were developed to assist the Project Coordinator with tracking progress of the study. Each study event is recorded through use of a checklist and data entry process on an ongoing basis. Data from the baseline and follow up HHQs are entered into the database by Informatics Core staff. The study staff enters study checklists which capture each study event as every participant completes it. Additionally, appointments for telephone sessions are scheduled and managed utilizing an MS Outlook calendar.

The 12-month follow up Health History Questionnaire is administered by telephone **(subtask i)** as participants reach the 12-month mark after their counseling session. The Informatics Core generates a call log after a participant has been in the study for 11 months, and study staff contacts participants to complete the follow up interview. The follow up HHQ takes approximately 30 minutes to complete over the telephone. Once this interview is completed, the participant has completed the study.

Task 3, is not applicable to the Year 5 Report as data collection is still in process. However, the subtasks are as follows:

a. Statistical analyses of data obtained
b. Publicize study findings
c. Prepare final report for granting agency

We have done some preliminary data analysis (**subtask a**) including preparation for various presentations (e.g. Era of Hope meeting) throughout the year. This includes descriptive statistics to characterize the study population, which can be found in the Reportable Outcomes section below.

KEY RESEARCH ACCOMPLISHMENTS

- Obtained informed consent on 26 new subjects, completed telephone counseling sessions with 27 subjects and completed 12-month follow up interviews on 28 participants during the past year.

A total of 519 potential participants have been contacted and of these, we have accrued and randomized 154 participants (81 tailored intervention group, 73 control group). Of these participants, 117 have completed the 12-month follow up and thus, the study.

Participant characteristics include:
Age: 41 (median) (range 25-77)
Race: 140 White; 10 African American; 2 Asian, 1 unknown, 1 other
Education level: 2 -8 to 11 yrs
35- High school or GED
5-Vocational or Technical school
50-Some College
40-Bachelor
14-Graduate
7-Doctoral
1-unknown

Participation in Family Risk Assessment Program: 2 tailored intervention group participant and 3 control group participants

- Attended and participate in monthly Center meetings.

- 12-month follow up Health History Questionnaires were administered to 28 subjects, completing their participation in the study

- Explored new recruiting procedures for identifying eligible breast cancer patients and their first-degree relatives.

- Amended protocol inclusion criteria to change definition of "newly diagnosed breast cancer patients" to 3-12 months from diagnosis in an effort to increase our pool of potential participants.

- The Leadership Core applied for and received DOD approval for a no-cost one-year extension.

REPORTABLE OUTCOMES

None

CONCLUSION

Subject recruitment continued at FCCC during the past year. We have continued to identify and refine recruitment procedures at both FCCC and the network site. We have established a consistent internal queue of women based on the appropriate time from diagnosis (e.g. 3-12 months) providing us with a steady flow of potential subjects to approach for participation in the study. We have identified the most effective recruitment strategies at FCCC and are using these as a model with the site. As of September 1, 2006 we ceased identifying breast cancer patients and their FDRs to allow for the currently enrolled FDRs to complete the study during the remaining year of the extended grant.

REFERENCES

N/A

DOD Progress Report, Project III
Facilitating Re-entry Following Treatment for Primary Breast Cancer

Suzanne M. Miller, Ph.D., Principal Investigator
Joanne S. Buzaglo, Ph.D., Co-Investigator
Andrea Barsevick, D.N.Sc., R.N., AOCN, Co-Investigator
Lori J. Goldstein, MD, Co-Investigator
Ramona Swaby, MD, Co-Investigator

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

As screening and surveillance for breast cancer has increased and treatment improved, the number of survivors of primary breast cancer has increased substantially (ACS, 2000; Pandey et al., 2000). The 5-year relative survival rate for localized breast cancer has increased from 72% in the 1940s to 96% today (ACS, 2000). Further, 71% of women diagnosed with breast cancer survive 10 years, and 57% survive 15 years (ACS, 2000). As the number of cancer survivors has increased, so too has the concern for the psychosocial adaptation of cancer survivors (e.g., Andersen, 1994; Ganz et al., 1996; Ganz et al., 1998; Gotay & Muraoka, 1998; Kornblith, 1998; Kurtz, Wyatt, & Kurtz, 1995; Schag et al., 1993; Wyatt & Friedman, 1996; Weitzner et al., 1997). However, little research has focused on easing the transition of individuals with early stage breast cancer from active treatment to follow-up care, referred to as the re-entry phase; even less research has focused on how individual differences moderate the process of adjustment to the challenges of survivorship (see Andersen, 1994; Helgeson et al., 2000). Guided by the Cognitive-Social Health Information Processing model (Miller, Shoda, et al. 1996; Miller, Mischel, et al. 1996), the primary objective of the proposed study is to develop and evaluate a tailored Cognitive-Affective Processing (CAP) intervention to facilitate psychosocial adjustment at re-entry following adjuvant treatment for primary breast cancer (Miller, 1995; Miller, 1996; Miller, Shoda, & Hurley, 1996; Miller, Fang, et al., 1999).

The specific aims for Project 1 are as follows:

Aim 1: To develop and evaluate a theory-based, individually tailored Cognitive-Affective Processing (CAP) intervention to facilitate re-entry following adjuvant treatment for primary breast cancer.

Aim 2: To examine the moderating effects of individual differences in attentional style (i.e., high vs. low monitoring) on the impact of the proposed intervention.

To reach the primary objective of the proposed study, three focus groups were conducted during Phase I of the study. Eighteen women from the target population (early stage, primary breast cancer patients) participated in the focus groups. The goal of the focus groups was to facilitate the development and refinement of the CAP intervention and the measures. The first two focus groups were designed to explore and assess the challenges confronted by the study population during the transition from being an active patient in treatment to a breast cancer survivor, i.e., the 're-entry' phase. Specifically, focus group participants were asked to discuss their perceived risk, expectancies and beliefs, values and goals, emotions, and coping strategies regarding their transition into 'survivorship'. Specific areas targeted included their cognitive-affective responses to cancer recurrence, cessation of treatment, sexuality, body image, and personal relationships. This information was used to further refine the intervention and measures. The final focus group was designed to obtain final suggestions for the improvement of the intervention and the battery of measures.

During Phase II, women (N=300) who have been diagnosed with Stage 0, I, or II breast cancer and are being treated at Fox Chase Cancer Center (FCCC) will be contacted for participation. Potential participants will be identified through the scheduling office at the Breast Cancer

Evaluation Clinic at FCCC and will be recruited near the completion of their adjuvant treatment. After they have been given a description of the study, participants who meet eligibility criteria and wish to participate will be asked to sign a consent form. Consenting participants will be randomized into either the intervention or control condition. All consenting participants will receive the intervention or control session during a post-adjuvant treatment follow-up medical visit. A booster session will be given two-weeks post-counseling intervention. All participants will be assessed via mail at one, six and twelve months post-intervention. The health educator will contact the participant by phone to collect follow-up data in the event that participants do not return the questionnaires within 2 weeks.

BODY

As outlined in our Statement of Work, Task 1 involves coordinating with the Communications Core in the testing and subsequent refinement of the cognitive-affective intervention designed to facilitate "re-entry" into the post-treatment phase of breast cancer for early stage breast cancer patients. This was to be accomplished through the use of focus groups to test both the intervention and the measures, with the Communications Core leading the process. The specific aims of Task 1 were to:

a. Recruit Focus Group Participants for Phase I
b. Conduct Focus Groups
c. Analyze Focus Group Data
d. Refine Interventions/Measures
e. Conduct Focus Groups to Evaluate Refined Interventions/Measures
f. Establish Recruitment Procedures/Staff Training

The responses from the three focus groups, in addition to comments and suggestions made by an external review committee, were used to refine the barriers intervention. While the intervention continues to addresses the cognitive-affective mediating units of participants, there is now a more refined assessment of the primary concerns and issues of breasts cancer survivors as well as the barriers to re-entry, which will be thoroughly addressed in the intervention session, with particular attention given to focus group participants' preferences for the timing of the delivery of the counseling intervention and the method by which the intervention will be delivered. Specifically, the intervention is delivered soon after the completion of adjuvant treatment with follow-up assessments conducted at the one-, six-, and twelve-month time points. The intervention draws heavily from the NCI publication, Facing Forward, and is consistent with its philosophy of taking an active role in recovery in combination with accepting changes that are beyond the patient's control. Further, the intervention provides strategies for coping with barriers to the re-entry phase of recovery and participants receive additional resources for dealing with their concerns. Revisions to the originally approved protocol were approved by the FCCC IRB in May 2004

Because the information obtained from three focus groups was adequate to modify the barriers intervention, an amendment was submitted to conduct a pilot study (N=20) in place of the fourth focus group. This modification was also approved in May 2004. The recruitment for the pilot

study was initiated during the past year in order to provide an evaluation of both the initial assessment and the revised intervention in terms of their thoroughness, applicability and feasibility. To enhance accrual rates for the study, recommendations were obtained from FCCC specialists (i.e., physicians, nurses, technicians) working with women with breast cancer towards the end of their treatment, in order to find more efficient ways to reach potential participants for the study. Based on the input received, the following amendments to the study protocol were submitted to the FCCC IRB/RRC and DOD IRB:

a. Amendment #5: Change to eligibility criteria

In an effort to enhance recruitment, we proposed to expand the study eligibility criteria to include women up to three months following their last adjuvant treatment appointment rather than 3-4 weeks post-treatment. The differences in the amount of time since completing treatment among participants will be taken into account in data analysis. Submitted to FCCC IRB/RRC on March 30th, 2005, and received approval on April 5th, 2005. Submitted to the DOD on April 7th, 2005, resubmitted on October 5, 2005 and received approval on November 16, 2005.

b. Amendment #6 regarding recruitment materials

In an effort to facilitate recruitment of participants two recruitment materials were created: a brochure and a physician card. The brochure, to be displayed in the Radiation Treatment, Chemotherapy and Outpatient Clinic at FCCC, targets potential participants and contains study's description and contact information. The physician card targets medical staff working with patients with breast cancer and contains eligibility criteria, study description and contact information. Amendment was submitted to FCCC IRB/RRC on May 31st, 2005, and was approved on May 26th, 2005. Amendment was submitted to the DOD on June 28th, 2005. Approval from the DOD was received on October 20th, 2005.

c. Amendment #7: Measure instruments: replacement and additions to the set of study measures

One study measurement "Health Protective Behaviors" will be replaced by "Behavioral Action Taken", a study specific measure designed to assess the extent to which patients engage in the actions recommended by "Facing Forward" book – a publication designed especially for breast cancer survivors by the National Cancer Institute. This author-constructed measure consists of five sections, each reflecting a chapter covered in Facing Forward, designed to assess the adoption of specific actions recommended in Facing Forward (i.e., using a follow-up guide to keep track of appointments, developing a plan to fight fatigue, using a pain diary to track pain levels). Patients are simply asked to report "Yes or No" with regard to engaging in each of the recommended actions. This measure will be administered at baseline and at all three follow-ups. The rationale for proposing the replacement of "Health Protective Behaviors" measure with "Behavioral Action Taken" measure is that: 1) The "Behavioral Action Taken" measure targets health protective behaviors that participants in both control and experimental group have been informed about through the Facing Forward publication; 2) The "Behavioral Action Taken" measure has been design in such a way to assess engagement in health protective behavior before and after the intervention. Another minor change proposed regards "Cancer-Related Benefits" Scale. We omitted to list it in Table III, on page 17-18: Provisional Measures and Times of Administration. This measure is now included in

Table III, and it is described in the body of the proposal. Amendment was submitted to FCCC IRB/RRC on August 9th, 2005 and approval was received on September 29, 2005. An amendment was submitted to the DOD on October 5th, 2005and approval was received on November 2, 2005.

d. Amendment # 8: Delivery of the intervention over the phone
Given the high patient refusal rate to participate in this study has been often justified by lack of time to come for an in-person counseling session, this amendment proposed to offer participants in the study the option to chose between an in-person counseling session or an over-the-phone counseling session. The counseling intervention can be appropriately delivered over-the-phone, since is an educational counseling session designed to be easily transportable. Amendment was submitted to FCCC IRB/RRC on August 9th, 2005 and approval was received on September 29, 2005. An amendment was submitted to the DOD on October 5th, 2005 and approval was received on November 2, 2005.

e. Amendment #9: Extending eligibility criteria
Given the difficulty of reaching patients once they have finished adjuvant therapy, this amendment proposes to modify study eligibility criteria as to be able to recruit breast cancer patients while undergoing adjuvant therapy and/or within one year of their end of treatment. Amendment submitted to FCCC IRB/RRC on August 9th, 2005 with approval received on September 29, 2005. An amendment was submitted to the DOD on October 5th, 2005 and approval was received on November 2, 2005.

Task 2 involves conducting the revised randomized trial (N=300) comparing the Cognitive-Affective Preparation (CAP) protocol designed to address the barriers to "re-entry" into the post-treatment phase of breast cancer for early stage breast cancer patients. The CAP intervention will be compared with a General Health Information (GHI) control to equate for time and attention. The specific aspects of Task 2 are to:

a. Recruit Participants, Randomize to Treatments, Test Interventions
b. Participants Eligible for Genetic Testing will be Referred to the Genetic Susceptibility Testing Laboratory Core

Task 2 was initiated upon completion of the pilot study. Eleven pilot participants completed the baseline assessment. The pilot study demonstrated the feasibility and credibility of the intervention. Therefore, we retained the 9 pilot participants who completed the two-week booster session for the ongoing main study and started recruitment for Task 2 in January 2006. Given the challenge of recruiting participants for the pilot study, as of September 2005, several strategies to enhance recruitment were developed as outlined above. Implementation of these strategies was delayed due to the complex IRB approval process from both FCCC and the DOD.

Our team attended several consultation meetings with the Informatics Core to initiate the database edifice, and to adjust it in accordance with modifications to the protocol. The Informatics Core designed and developed Project 3's (baseline) application. In the past year, the follow-up database and data entry interface(s) plus analytic views were initiated.

Task 3, involves conducting data analyses on all data collected and presenting/publishing findings. Due to delays in the revision and approval of the intervention, there is not enough data collected to complete this task. To allot for the extra time that will be needed to collect additional data and complete task 3, we requested an additional no-cost extension to continue this study in 2007

a. In collaboration with the Informatics Core, Statistical Analyses of Data Obtained
b. Publicize Study Findings
c. Prepare Final Report for Granting Agency

KEY RESEARCH ACCOMPLISHMENTS

- Continue to attend and participate in monthly Center meetings

- Conducted meetings with FCCC Outpatient Clinic, Breast Cancer Clinic, and Ambulatory Care - Infusion Room staff (physicians, nurses, technicians) in order to get their input and support for increasing participation in the study.

- Developed recruitment materials (i.e. physician cards, brochures) in order to better reach potential participants.

- Submitted revisions to the FCCC IRB regarding use of recruitment materials, and extension of eligibility criteria in order to increase study accrual. Submitted the FCCC IRB approved revisions to the DOD and Approval is pending.

- Revised the study measures based on the preliminary information from the pilot study. "Behavioral Action Taken" will replace the "Health Protective Behaviors" measure upon FCCC and DOD IRB approval. This is a study specific measure designed to assess the extent to which patients engage in the actions recommended by "Facing Forward" book – a publication designed especially for breast cancer survivors by the National Cancer Institute.

- Submitted a new HIPPA authorization form using a new template developed by the FCCC IRB to DOD for approval.

- Data collection procedures were established with the Informatics Core to initiate the database edifice.

- 14 patients were recruited for and provided written consent for the pilot study. Pilot baseline data was collected for 11 participants. Of these 11 initial pilot participants, 10 participants completed the intervention, 9 completed the 2 week booster session, 6 completed the one month follow-up, 4 completed the six month follow-up, and 2 completed the 12 month follow-up. The pilot participants that completed the 2-week booster session were retained as participants in the ongoing study.

- Including the pilot study, 178 patients were evaluated for eligibility and 63 eligible participants were approached. 41 participants gave verbal consent, 24 provided written consent, 20 completed the baseline survey, 17 completed the intervention, 15 completed the 2 week booster session, 10 completed the one month follow-up, 5 completed the 6 month follow-up, and 2 completed the 12 month follow-up.

- Additional staff were trained in recruitment procedures so that recruitment calls could be made more often on different days of the week. Evening recruitment calls were also initiated for participants who could not be reached during business hours.

- The Leadership Core applied for and received DOD approval for a no-cost one-year extension.

REPORTABLE OUTCOMES

-none

CONCLUSION

Data collection will continue. With the additional one-year extension, the additional staff, and the increased recruitment calls we anticipate no further obstacles in the progress of this project.

REFERENCES

N/A

DOD Progress Report, Project IV
Communication Skills Versus a Supportive Therapy Intervention for Women with Metastatic Breast Cancer

Dr. Sharon Manne, Ph.D., Principal Investigator
Dr. Karthik Devarajan, Ph.D., Statistician

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

Excluding skin cancers, breast cancer is the most common cancer diagnosed in American women. Recent advances in early detection and treatment have resulted in higher cure rates for breast cancer. Unfortunately, approximately 6% of breast cancer patients develop metastatic disease (stage IV). For the majority of women diagnosed with metastatic breast cancer, median survival is approximately 18 to 24 months with systemic chemotherapy. The overall five-year survival rate for women with stage IV breast cancer is 21.3%. Thus, although a cure is not achieved for most patients, treatment improvements have made it possible for women to survive for relatively long periods of time with stable disease. Consequently, symptom relief and improvement in quality of life are critical therapeutic goals for this population.

The specific aims for Project 4 are as follows:

Aim 1: To compare the effectiveness of a communication and support skills intervention versus a supportive therapy intervention on the quality of life of women with metastatic breast cancer.

Aim 2: To explore the effects of individual differences (e.g., ambivalence over emotional expression), treatment expectancies, social support and coping on the impact of the interventions.

This is a multi-site study, with prospective subjects being identified at the Fox Chase Cancer Center (FCCC), Cooper Health System Division of Hemotalogy/Oncology, Temple Cancer Center, and Bryn Mawr Hospital (BMH) of the Main Line Health System. On-site physicians regularly provide the research assistant with a list of eligible patients who have given permission to be contacted for this study. Eligible participants are mailed a letter describing the study. Patients are approached and contacted in person by the Research Study Assistant during a clinic appointment, and the study is described in more detail. If the participant is interested in participating, informed consent will be obtained at that time. After obtaining written informed consent, the pre-intervention assessment packet is administered.

The study design is a randomized clinical trial with two study conditions: 1) Communication and Support Skills intervention, 2) Supportive counseling intervention. Patients are assigned to one of these conditions after the initial packet has been completed. The intervention programs are administered in an individual format with six in-person sessions and one telephone follow-up. Assignment is stratified into groups having low or high baseline psychological distress as determined by the Beck Depression Inventory.

The goal of this study is to determine whether an intervention targeted to women with breast cancer can impact their psychological distress. We have utilized a structured, CBT-oriented intervention that teaches effective communication and support skills because this type of intervention will assist patients in obtaining support from their existing support networks (rather than from other patients). Prior studies have suggested that deficits in support from partners and a lack of open engagement with partners are particularly problematic for female, late stage patients and among metastatic breast cancer patients. We have selected supportive psychotherapy as a comparison condition because this intervention will not provide skills, but will provide emotional support. In addition, this condition will provide a control for the non-specific effects of therapy (therapeutic bond, treatment expectancies, time and attention spent on the patient). We

will examine the role of these non-specific factors in treatment outcome. We also will assess adherence to treatment protocol and treatment discrimination, which have been ignored in prior research. By focusing an individual difference variable (lack of support) that has been shown to predict a beneficial outcome for interventions, we may be more likely to elicit a response to treatment that has not been consistently found in prior studies of metastatic breast cancer patients.

BODY

Below are the specific tasks to be accomplished, as originally outlined in the Statement of Work, in the context of this Project 4. .

Task 1:

To refine the intervention manual for the support skills intervention and train psychotherapists in administration of both interventions.

a. Recruit Focus Group Participants
b. Conduct Focus Groups
c. Analyze Focus Group Data
d. Train therapists in both conditions
e. Prepare study questionnaires, recruitment materials, materials for therapists

Task 2

a. Recruit participants
b. Administer study questionnaires
c. Conduct intervention sessions
d. Regular therapist supervision meetings
e. Enter study data
f. Conduct follow-up assessments
g. Treatment integrity checks

Based upon previous experience, Project 4 staff determined that focus groups would prove redundant to earlier work and experience conducted with this patient population. Therefore, in place of the focus groups (Task 1a, 1b and 1c) staff regularly met with the study interventionists in order to develop and tailor the intervention material. The training of project therapists (1d) was completed as scheduled. Though questionnaires and therapist materials were completed as scheduled (1e), there was some delay and in the production of recruitment materials due to nature of the multi-site IRB approval process. Materials have included posters, letters (signature stamped by prospective participant's oncologists), pamphlets, and stickers to be attached to eligible patients medical charts. Currently all recruitment materials have been approved.

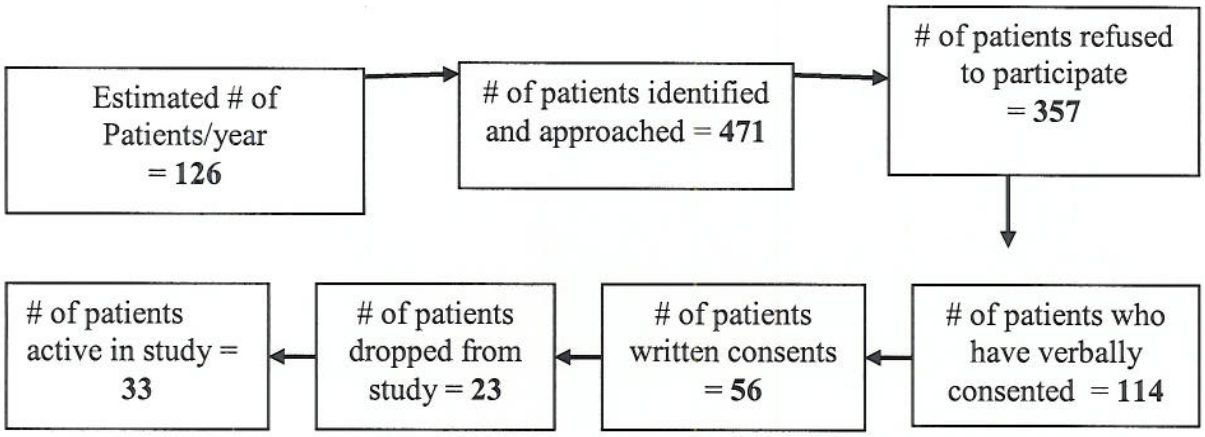
Though recruitment (2a) has begun, there was approximately a 4-month delay in start-up due to multiple protocol amendments, and their respective DoD and multi-site IRB approval

requirements. Study questionnaires and conducting of intervention sessions (2b, 2c) commenced after the start-up delays, and has kept pace with recruitment. The PI and Project Manager have begun regular therapist supervision (2d) with the interventionists throughout the year. Data entry (2e) has been done concurrently with recruitment and intervention sessions. Project 4 staff has worked closely with the Informatics Core in order to develop data entry protocols, computerized data entry form screens, and a system which allows Project 4 staff to be automatically notified when different questionnaire elements are due to be sent to patients. Follow-up assessments and treatment integrity checks (2f, 2g) are being conducted on a regular basis. Intervention sessions are audio taped for treatment integrity-tracking purposes.

Sluggish recruitment continues to be a significant issue in the fifth active year of the Project 4 despite efforts to increase enrollment by approaching patients in-person and increasing awareness of our project among the oncologists treating patients at Fox Chase Cancer Center. Identification and recruitment figures continue to be lower than originally anticipated. Low recruitment figures continue to stem from two primary causes; 1) we have identified fewer eligible individuals than previously estimated, and 2) we have experienced a higher refusal rate than anticipated. Below, in Figure 1, we summarize our recruitment efforts to date. Our sample size at this point is 53. 29 women have been assigned to the Communication and Support skills condition and 24 women have been assigned to the supportive condition. Of the 29 women assigned to the Communication and Support skills condition, twenty have completed all six sessions and nine have dropped out of study. Of the 24 assigned to the Supportive counseling condition, seventeen women have completed all 6 sessions and seven have dropped out. Thirty-five of our 53 participants have completed the first follow up and twenty-eight have completed the second follow up survey. Participant characteristics include:

- 53 breast cancer patients enrolled to date
    - 29 in Communication and Support Skills Counseling
    - 24 in Supportive Counseling
- Primarily Caucasian
    - 88% Caucasian, 8% African American, 2% Hispanic, 2% Multi-racial
- Average age: 58.39, range = 36 - 81
- Primarily well-educated
    - 0 - 4 years of school - 2%
    - 5 - 8 years of school - 2%
    - Finished high school - 37%
    - 1 - 3 years of college - 21%
    - Bachelors' Degree - 4%
    - Trade of Business School - 10%
    - Some Graduate School - 10%
    - Graduate Degree - 14%

Figure 1: Summary of Recruitment Efforts through 9-2003



In terms of other study tasks, all session audiotapes are being coded for integrity by Jeanne Schueller, our project manager. All study data has been entered to date, and supervision of study therapists has been both ongoing via feedback from Sharon Manne to each therapist as well as accomplished by in person supervision meetings every 3-4 months.

KEY RESEARCH ACCOMPLISHMENTS

- Attend and participate in monthly Center meetings.
- Actively recruiting patients, both at FCCC and satellite sites.
- Actively administering the experimental interventions.
- Further development and tailoring of the interventions.
- Trained the interventionists.
- Further development of the recruitment procedures.
- Finalization of study assessment instruments.
- Utilized Informatics Core to develop and maintain data collection and management procedures.
- The Leadership Core applied for and received DOD approval for a no-cost one-year extension.

REPORTABLE OUTCOMES

Aside from our recruitment activity, summarized in Figure 1, we do not have additional reportable outcomes at this point.

CONCLUSION

Task 1study elements have been completed. Task 2 elements, including recruitment, intervention, treatment integrity and supervision, and data collection and entry are well underway. In the last four years we have made significant efforts to boost enrollment by adding a number of local hospitals to our study as well as by increasing awareness of our project among the oncologists treating patients at Fox Chase Cancer Center. In addition, we have been recruiting patients through in-person approaches when they come to the clinic for treatment. This effort has addressed some of the enrollment problem but because we are dealing with a very ill population it is likely unrealistic to expect a high enrollment. We have made efforts to reduce study burden by reducing questionnaire length and adding subject incentives, to reduce refusal rates. We estimate that preliminary data analysis will begin sometime in the next reporting year (10/2006-10/2007). Thus, no analytical conclusions can be drawn at this time.

REFERENCES

N/A

DOD Progress Report
Leadership Core

Dr. Suzanne M. Miller, Ph.D.
Principal Investigator
Core Director

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

Under the direction of the Leadership Core, the development of the Behavioral Center of Excellence in Breast Cancer (BCE) has been guided by a unifying cognitive-affective processing (CAP) approach to breast cancer prevention and control that has informed the specific hypotheses of each project and has dictated the relevant interventions and assessments, and that provides a multidisciplinary linkage across projects. The senior leadership and administrative support core component is designed to ensure scientific collaboration, guidance, and integration across the research projects and to promote the efficient administration of all the components of the BCE grant. Through collaboration between the principal staff on the main projects and other cores, the Leadership Core is able to broaden past and ongoing research by pursuing a closely coordinated research program to modify attitudes, behavior patterns, and lifestyles in ways that will ultimately reduce breast cancer incidence, morbidity and mortality effectively, thus directly addressing the mission for consequential behavioral research in breast cancer.

The specific aims of the Leadership Core are as follows:

Aim 1: To provide oversight, and management of, all aspects of the BCE to maximize the efficiency of its integrative, inter-coordinated organizational structure.

The Leadership Core for the BCE is intended to be a resource to the Center as a whole, as well as to function as the administrative resource for each of the individual projects.

Aim 2: To continue to develop, refine, and evaluate the overarching, unifying conceptual framework.

In order to continually refine the guiding theory of research within the BCE, the Leadership Core will integrate data across projects to more comprehensively address the dynamics of the interactions between construals and the other cognitions and affects that they prime and activate within the processing system, as the individual interprets, transforms, and acts on diverse types of cancer risk information (Miller & Diefenbach, 1998).

Aim 3: To oversee and enhance the centralized quality control mechanism for designing, refining, and evaluating the theoretically derived assessments and interventions.

The Leadership Core will function to ensure that the project investigators create and tailor the Cognitive-Affective Preparatory interventions to target the entire pattern of intervening cognitive and affective dynamics that underlie effective modulation of distress and long-term adherence to breast cancer prevention-control behaviors.

Aim 4: To develop actuarial predictive indices of cognitive-affective processing types.

With oversight from the Leadership Core, a goal of the BCE is to clarify and harness Person x Situation interactions emphasized by the C-SHIP model. This requires a shift from global to specific, contextualized analysis and assessments.

Aim 5: To oversee and guide the planning, development, and implementation of new BCE projects.

By building on the strong network of projects already proposed, the vision of the BCE is to develop further studies that are relevant to the CAP agenda and that interact synergistically with the ongoing work.

Aim 6: To administer the Training Program.

The Leadership Core will oversee the implementation of the pre- and post- doctoral training program through the identification of qualified candidates with ambitions to pursue careers in behavioral medicine and the development of communications to enhance cancer prevention and control.

BODY

According to our Statement of Work the plan during Years 2 through 3 was to accomplish the following tasks: 1) to convene Advisory Committee and scientific meetings; 2) to oversee implementation of core functions and to oversee initiation of projects and cores; 3) to implement the Training Program and, 4) implement meta-analysis and thematic integration of findings

Task 1. To convene the advisory committee and scientific meetings.

First, the External Advisory Committee, which was chosen to provide consultation for the BCE senior staff, held its first meeting in December 2002 at FCCC. Dr. Howard Leventhal, Board of Governors Professor of Health Psychology, and Director of the Institute of Health, Policy and Aging Research at Rutgers University provided expert consultation in the theoretical application of cognitive-social principles to the assessment and development of the study interventions. Dr. Chanita Hughes, Assistant Professor in Psychology at the University of Pennsylvania provided expert consultation in cultural sensitivity with respect to intervention development and minority recruitment. The Committee is scheduled to re-convene in April 2007.

Second, Dr. Miller, Director of the BCE, continues to involve the Behavioral Center of Excellence in the organization of several national groups. This includes leading the Behavioral Oncology Interest Group at the American Society for Preventive Oncology. Dr. Miller, a Member of the Steering Committee, co-chaired the 2006 Annual Meeting of ASPO in Bethesda MD with a Pre-conference Day on Numeracy, entitled: "What Numbers Could Be: The Role of Numeracy in Understanding and Communicating Cancer Risk and Management Information". This meeting consisted of talks followed by roundtable discussions facilitated by behavioral scientists to focus on advances at the intersection of behavioral science and oncology, and allowing interchange and discussion of behavioral science issues as they relate to cancer prevention. Dr. Miller was also a leading organizer of 2005 Society of Behavioral Medicine Cancer Special Interest Group (SIG) Pre-conference Day Roundtable Sessions on Decision Making in Cancer (Annals of Behavioral Medicine, November 2006). The Annals of Behavioral Medicine is dedicating a special series to this Decision Making in the Cancer Context Pre-

Conference Day with Dr. Miller as a guest editor. In 2006, Dr. Miller organized the 2006 Cancer SIG Pre-conference Day, *Health Disparities: Future Directions for Behavioral Medicine.* The results of this session are currently being prepared for publication. Dr. Miller is currently planning the 2007 Cancer SIG Pre-conference Day, *Cancer and Aging: Challenges and Opportunities Across the Cancer Control Continuum.*

Third, Dr. Suzanne Miller and other members of the BCE team presented a paper from the BCE projects, *Decision making among high risk women undergoing breast/ovarian genetic testing*, at the Annual Meeting of the Society of Behavioral Medicine, San Francisco, CA. March, 2006.

Fourth, the Leadership Core has established the Behavioral Medicine Speakers Series at Fox Chase Cancer Center. The following speakers were invited to present their most current data to the Division of Population Sciences:

- Dr. Karen Hurley, Memorial Sloan-Kettering Cancer Center, spoke on, "Person-centered theories: New directions in behavioral oncology research" on December 6, 2005.
- Dr. Karen Sepucha, Massachusetts General Hospital/Harvard Medical School Health Decision Research Unit spoke on, "Understanding and Improving the Quality of Breast Cancer Treatment Decisions" on January 17, 2006.
- Dr. Catharine Wang, Fox Chase Cancer Center, spoke on, "Public Health Efforts in Familial Risk Assessment" on February 14, 2006.
- Dr. Carolyn Fang, Fox Chase Cancer Center spoke on, "Mindfulness-Based Interventions to Enhance Health" on April 4, 2006.
- Dr. Paul Han of National Institutes for Health spoke on, "Predictors of Decisions Between Risk Reducing Salpingo-Oophorectomy and Ovarian Cancer Screening in Women at Increased Risk of Ovarian Cancer" on September 12, 2006.

Dr. Miller and Dr. Buzaglo continue to work with the FCCC Community Clinical Oncology Program (CCOP) Research Base to expand hospital-based research into the community. Through the simulation of research efforts into the community, the FCCC CCOP Research Base will provide cancer patients, their families, and high-risk individuals access to new prevention and control studies closer to home. CCOP investigators are currently conducting an intervention for breast cancer survivors using the NCI publication Facing Forward, "Efficacy and Feasibility of a Psychosocial Intervention within the CCOP Context: Evaluation of the Facing Forward Guide to Facilitate Life after Active Cancer Treatment".

Dr. Miller continues to serve as a member of the Board of Directors of the New Jersey Health Care Quality Institute and as a member of the National Quality Forum's *Quality of Cancer Care Measures* project where she serves on the Symptom Management/End of Life Care Technical Panel. In addition to symptom management and end-of-life care, this project focuses on colorectal and breast cancer diagnosis and treatment. The Technical Panel is charged with conducting an initial assessment to evaluate candidate performance measures for their validity, which must occur before the Project's Steering Committee will consider recommending the measure to the National Quality Forum for endorsement.

Task 2. To oversee implementation of core functions and to oversee initiation of projects and cores.

The Leadership Core continues to hold monthly BCE meetings. Principal Investigators, Co-Investigators, Project Managers of the various BCE projects and Core staff attend these meetings that provide an opportunity for investigators to exchange ideas and provide input across studies. Agenda items include: 1) Updates from each project and core; 2) Training Program status; 3) DOD reporting requirements and IRB documentation; 4) Standardization of assessment tools across studies to maximize opportunities for meta-analysis; and 5) Cooperative strategies to enhance recruitment across studies. Meetings minutes are kept to record the current status of each study. Specifically:

- Recruitment for Phase 2 of project 1 is ongoing. Two hundred twenty one calls were received, but only 85 callers met the eligibility criteria, and out of these 50 consented to participate in the study. 35 have completed baseline surveys and 23 have completed 6-moth follow-up surveys. Amendments were submitted and approved by the FCCC and DOD IRBs to exclude the criteria pertaining to one's income and broaden the eligibility criteria to include second degree relatives. Radio and newspaper advertisements are no longer being utilized. Four sites have agreed to allow us to recruit through their organizations using flyers. These sites include community and religious organizations, a health seminar, and a breast cancer survivors mentorship program. An amendment was submitted to the FCCC IRB in September 2006, and is currently awaiting approval. Upon approval by the FCCC and DOD IRB, flyers will be distributed to the four sites inviting potential participants to call the toll free telephone number. We anticipate this new recruitment strategy will assist us in our continuing efforts to accrue the desired sample.
- Recruitment for Project 2 is still in progress. A total of 519 potential participants have been contacted and of these, we have accrued and randomized 154 participants (81 tailored intervention group, 73 control group). Of these participants, 117 have completed the 12-month follow up.
- Due to low study accrual rates in project 3, several amendments (e.g., use of recruitment materials such as physician card, brochure, modification in eligibility criteria and delivery of intervention) to the protocol have been submitted and approved by the FCCC and DOD IRB. The pilot study portion has been completed and 178 patients were evaluated for eligibility. 63 eligible participants were approached. 24 provided written consent and completed the baseline survey, 18 completed the intervention, 9 completed the one month follow-up, 5 completed the 6 month follow-up, and 2 completed the 12 month follow-up. To increase recruitment, additional staff were trained in recruitment procedures so that recruitment calls could be made more often on different days of the week. Evening recruitment calls were also initiated for participants who could not be reached during business hours.
- Recruitment for Project 4 is still in progress. Identification and recruitment figures continue to be lower than originally anticipated. The staff continues to recruit all eligible patients and collect first and second follow-up surveys. Our sample size at this point is 53. 29 women have been assigned to the Communication and Support skills condition and 24 women have been assigned to the supportive condition. Thirty-five of

our 53 participants have completed the first follow up and twenty-eight have completed the second follow up survey

Task 3. To implement the Training Program.

The following has been implemented to support the BCE Training Program:

The Leadership Core holds the responsibility of disseminating an announcement about pre- and post-doctoral fellowship opportunities, developing an evaluation procedure, arranging for candidate interviews, selecting candidates, and training the post-doctoral fellows. The following review criteria are used to evaluate potential candidates: Ability in Written Communication, Familiarity with Behavioral Oncology in General, Familiarity with Breast Cancer in Particular (Behavioral and Medical issues), General Research Experience, Apparent General Research Proficiency, Commitment to Research Career in Behavioral Oncology/Cancer Prevention and Control, Quality and Relevance of Academic Training, Enthusiasm for Fellowship, Convergence Between BCE Projects and Applicant's Experience, Convergence Between BCE Projects and the Applicant's Career Goals.

Pagona Roussi, Ph.D., returned to the Psychosocial and Behavioral Medicine Program in September/October 2004,September 2005, and September/October 2006. Dr. Roussi has been serving as a trainee with Dr. Miller and members of the research team on several ongoing grants. Dr. Roussi comes from Aristotle University of Thessaloniki, Thessaloniki, Greece offering expertise in stress and coping with major life events, with a special interest in serious illnesses. Dr. Roussi has a Ph.D. in Chemistry earned at Imperial College, London University, London, England in 1977. Since earning her Ph.D. in Clinical Psychology at Temple University, Philadelphia, Pennsylvania in 1995 Dr. Roussi has taught in the Department of Philosophy and Social Studies at the University of Crete, Crete, Greece as a Visiting Assistant Professor as well as in the Department of Psychology at Aristotle University of Thessaloniki, Thessaloniki, Greece. She has several publications, both independently and in collaboration with Dr. Miller and other Investigators. Her responsibilities at FCCC include analyzing data, writing manuscripts, and providing consultation and assistance with the designing of new interventions. Specifically, she has been involved in the development of the intervention protocol for Project 3 and for data-analytic plans.

Mary Ropka, Ph.D., R.N., F.A.A.N., joined the faculty at Fox Chase in May 2004 as an Associate Member in the Division of Population Science and has been involved in BCE as a mentee. She also holds adjunct appointments as Associate Professor in the Department of Health Evaluation Sciences at the University Of Virginia School Of Medicine and in the School of Nursing. Dr. Ropka is a clinical epidemiologist and oncology nurse who has a long-standing track record of interdisciplinary work and building new research programs and teams. She has experience with diverse study approaches, including multi-site clinical trials, survey research, observational designs, focus group studies and other qualitative approaches, and systematic reviews. Dr. Ropka's recent work, funded by a 5-year K07 Cancer Prevention (2001 – 2006), Control, and Population Sciences Career Development Award from NCI, is focused on decision support, behavioral cancer genetics, and cancer prevention and control in order to develop and test patient decision support interventions related to hereditary cancer risk. Dr. Miller is Co-

Sponsor for her K07. In addition, Dr. Ropka is assisting Dr. Miller on the following: (1) developing the Signature Program proposal at Fox Chase focused on Health Decision Making; (2) the Behavioral Research Core Facility, of which Dr. Miller is the Director; (3) Dr. Ropka's K07 study, "Decision Making Needs and Family Communication When Dealing With Hereditary Cancer Risk Decisions – A Qualitative Pilot Study", for which Dr. Miller is a co-investigator; (4) Dr. Ropka's June 2005 R21 application, "Facilitating Web-based Decision Support For Hereditary Cancer Risk"; (5) CISRC grant funded by NIH, of which Dr. Miller is PI of the Intervention Development and Measurement Core; (6) conducting a half-day pre-conference Cancer Special Interest Group session at the annual Society for Behavioral Medicine meeting in April 2005, "Decision Making in the Cancer Context – Translation from Basic Science Through Population Health", for which they have co-edited a special series which will appear in the *Annals of Behavioral Medicine*; and (7)submitting an R21 grant proposal for which Dr. Miller is a co-investigator: "Benign Breast Disease: Cognitive-Affective Responses and Risk Reduction Behaviors " in response to Program Announcement PA-06-351, "Exploratory Grants for Behavioral Research In Cancer Control (R21)".

Catharine Wang, Ph.D. joined the Psychosocial and Behavioral Medicine Program in August 2005 as an Assistant Member in the Division of Population Science at FCCC and is involved as a mentee in the BCE. She has an extensive background in developing and evaluating tailored interactive multimedia and behavioral interventions. Prior to her appointment at FCCC, Dr. Wang was involved in several projects in collaboration with the Health Media Research Lab (now the Michigan Center for Health Communication Research) at the University of Michigan, led by Dr. Strecher. These projects included the development of an interactive CD-ROM program for BRCA1/2 education and counseling, and tailored health communication interventions to address multiple behavioral risk factors such as smoking cessation, physical activity and diet. In addition, Dr. Wang has a background in the area of decision research. She has collaborated with researchers at the University of Michigan to examine how various communication aids, such as graphic images or pictographs, may be used to improve the comprehension of risk communication and modify the influence of patient testimonials in treatment decision making. Dr. Miller is currently mentoring Dr. Wang in the application of theory to behavioral interventions and evaluation of public health programs related to breast cancer risk and survivorship.

Amy Lazev, PhD., joined the Psychosocial and Behavioral Medicine Program in July 2003 as an Assistant Member in the Division of Population Science at FCCC. She has been funded with an R25 NCI training grant with Dr. Miller as her mentor. She is a clinical psychologist with over 10 years of experience developing and conducting treatment outcome studies in smoking cessation. Her research has focused on special populations including pregnant and postpartum women, low-income and minority populations, college students, persons living with HIV/AIDS and cancer patients. She has been the Principal Investigator on an American Lung Association grant examining social support and depression among pregnant and postpartum women who smoke and on an American Cancer Society grant examining smoking behavior in the college-age population. She is currently collaborating with Dr. Miller and the Maternity Care Coalition, a community-based service and research organization, on a grant submission for a smoking cessation intervention for underserved pregnant and postpartum women. She is also applying for a K07 training grant with Dr. Miller as her mentor.

Pamela J. Shapiro, Ph.D., joined the Psychosocial and Behavioral Medicine Program in May 2006 as an Assistant Member in the Division of Population Science at FCCC. She previously held a Postdoctoral Fellowship in the Department of Psychiatry and the Abramson Cancer Center of the University of Pennsylvania. Dr. Shapiro is a cognitive psychologist whose research interests include the neurcognitive sequelae of cancer diagnosis and treatment, health-related quality of life, and issues of concern to women at risk for hereditary breast and ovarian cancers (HBOC). She recently submitted an NCI R03 proposal, *Psychosocial Predictors of Cancer-Related Cognitive Change*" to examine the real-life cognitive difficulties women with breast cancer experience across the cancer trajectory. She is currently working on a feasibility study for assessing cognitive impairment among chemotherapy patients and is developing a diathesis-stress model of cancer-related cognitive change for a K07 career development grant with Drs. Miller and Barsevick as her mentors.

Douglas Hill, PhD., joined the Psychosocial and Behavioral Medicine Program as a Senior Project Manager in February 2006. Dr. Hill has a doctorate degree in Social Psychology and a research background on health beliefs, changing health behaviors, and public health policy. He is being mentored by Dr. Suzanne Miller and Dr. Joanne Buzaglo within the BCE in research methodology and design, and behavioral oncology.

Etyia Faison, M. Ed., joined the Psychosocial and Behavioral Medicine Program as a Project Manager in June 2006. She has a counseling background in individual, group, and family therapy and a research background in nutritional and epidemiological research. She is being mentored by Dr. Suzanne Miller and Dr. Joanne Buzaglo within the BCE in research methodology and design, and behavioral oncology with an emphasis on healthcare disparities among racial/ethnic underserved minorities.

Jaime Marks, MS, joined the Psychosocial and Behavioral Medicine Program as a Health Educator in July 2006 after completion of her Masters in Human Development and Family Studies at Pennsylvania State University. She is being mentored by Dr. Suzanne Miller and Dr. Joanne Buzaglo within in the BCE in breast cancer research with an emphasis on survivorship and psychosocial correlates of cancer screening and prevention behavior among underserved populations.

Elizabeth Bernabeo, MPH, joined the Psychosocial and Behavioral Medicine Program in January 2004, and is involved as a mentee in the BCE. She currently holds a Master Degree in Public Health from Temple University and she is completing her Ph.D. in Social Welfare at School of Social Work and Social Research, Bryn Mawr College. Elizabeth Bernabeo is being mentored by Dr. Suzanne Miller and Dr. Joanne Buzaglo in decision-making process in cancer context, and psychosocial aspects of decision-making in the context of genetic testing. She is conducting her dissertation project: "Decision Making among High-Risk Women Undergoing Breast/Ovarian Genetic Testing" under the supervision and mentorship of Dr. Miller and Dr. Buzaglo.

Elizabetta Razzaboni, Ph.D., joined the Psychosocial and Behavioral Medicine Program in August 2004 and worked with the research team for eight weeks. She came to FCCC from the Department of Psychology at the University of Bologna, Bologna, Italy. She was actively involved in reviewing BCE focus group transcripts with a special focus on qualitative analysis. Drs. Miller and Buzaglo mentored her with respect to the application of cognitive-social theory

to the development of assessment and behavioral intervention protocols for women at high risk for breast and ovarian cancer. Dr. Razzaboni is a member of an interdisciplinary oncology team in Bologna established to create a program for state-of-the-art care for women at familial risk for breast and ovarian cancer and is continuing to work collaboratively with BCE.

Catia Ghinelli, Ph.D., returned to the Psychosocial and Behavioral medicine Program in August-September 2005 as a mentee in the BCE. She originally came to FCCC from the Department of Psychology at the University of Bologna, Bologna, Italy in the summer of 2003 at which time she translated study protocols related to breast cancer survivorship and lymphedema. She continues to collect data on women diagnosed with early stage breast cancer and is actively involved in comparing cross-cultural datasets relevant to the BCE. Drs. Miller and Buzaglo provide ongoing guidance in the data collection and analysis.

Chana Gorodischer, CSW, Coordinator of the Eshkol Breast Health Center, Soroka University Medical Center, Ben Gurion University of the Negev, Israel. Ms. Gorodischer spent a two-week internship in August 2005 to study the cognitive-social model utilized to develop and assess the BCE behavioral protocols with a special focus on BCE 3, *Facilitating Re-entry Following Adjuvant Treatment for Primary Breast Cancer* as well as a related study entitled *Efficacy and Feasibility of a Psychosocial Intervention within the CCOP Context: Evaluation of the Facing Forward Guide to Facilitate Life after Active Cancer Treatment* (P.I. Dr. Suzanne M. Miller). Both of these ongoing funded projects will provide the foundation on which to build a research program that assesses the psychosocial needs of women who have undergone treatment for breast cancer as well as the development of innovative health communications and evaluation of the comprehensive psychosocial programs already in place at the Soroka Breast Health Center in Beer Sheva, Israel.

The Summer Internship Program continues to operate. The Summer Internship program was established in 2002 to provide training opportunities to students at the high school, undergraduate and graduate levels in the area of behavioral research within the context of breast cancer prevention and control to encourage future leaders in the field and to provide a source of candidates for the Training Program. Three interns joined us in the summer of 2006: James Wise, a senior at Pennsylvania State University, joined FCCC in June 2006 as a research intern. He worked on integrity checks and date entry for project 3. Yana Anokhnia, a senior attending Bensalem High School in Bensalem, PA, joined FCCC in July 2006 and helped with screening participants for eligibility and with recruitment calls for project 3. Bridget Brady, a senior a Millersville University, joined FCCC in July 2006. She helped with screening participants for eligibility and recruitment calls for project 3, and with contacting organizations for project 1 Current yearly interns include Stacey Abraham and Marina Mathew, both high school students at Central High, Philadelphia. They are currently helping with screening participants for eligibility and recruitment calls for project 3

Task 4. To implement meta-analysis and thematic integration of findings.

An extensive meta-analysis will be conducted, as planned in Task 4, upon the completion of data collection for the studies within the BCE.

The Leadership Core has contributed an extensive list of articles based on its literature search on breast cancer risk to the library of the Behavioral Research Core Facility (BRCF) at Fox Chase Cancer Center under the direction of Dr. Suzanne Miller. The BRCF provides the necessary infrastructure and resources to integrate basic and applied bio-behavioral and psychosocial research across the spectrum of cancer prevention and control research. Its mission and function are synergistic with that of the BCE. The BRCF library serves as an NCI- funded resource to investigators throughout the institution.

KEY RESEARCH ACCOMPLISHMENTS

- The continuation of monthly BCE meetings.
- The following steps have been implemented to support the BCE training program:
    - The continuing support of the BCE Training Program Committee that oversees the development and implementation of promotional strategies to enhance recruitment of qualified candidates for the pre- and post-doctoral fellowships.
    - Pagona Roussi, Ph.D., returned to the Behavioral Medicine Program as a consultant on the various projects within the BCE.
    - Catia Ghinelli, Ph.D., joined the Behavioral Medicine Program in August 2005 as a visiting researcher providing consultation in cross-cultural data collection and quantitative data analysis for the projects within the BCE.
    - Pamela J. Shapiro, Ph.D., was hired to fill the remaining post-doctoral position within the Training Program. She previously held a Postdoctoral Fellowship in the Department of Psychiatry and the Abramson Cancer Center of the University of Pennsylvania . Her research interests include health-related quality of life, the cognitive sequelae of cancer diagnosis and treatment, and issues of concern to women at risk for hereditary breast and ovarian cancers (HBOC).
    - The establishment of a collaboration with the Eshkol Breast Health Center, Soroka University Medical Center, Ben Gurion University of the Negev, Israel to translate BCE protocols and develop innovative health communications and evaluation of the comprehensive psychosocial programs already in place at the Soroka Breast Health Center in Beer Sheva, Israel.
    - The Summer Internship Program and the Yearly Internship Program continued successfully for its fourth year in providing training opportunities to students at the high school, undergraduate and graduate level in the area of behavioral research within the context of breast cancer prevention and control to encourage future leaders in the field.

- The continuation of the Behavioral Oncology Interest Group at the American Society for Preventive Oncology (ASPO).

- Preparation and publication in 2006 of two volumes that will extend the theoretical model across the cancer continuum, including genetic risk, and provide an integrative synthesis of the behavioral medicine field. The titles of these volumes are: "Individuals, families and the new era of genetics: Biopsychosocial perspectives" and "Handbook of behavioral science and cancer"

- Collaboration with Al Marcus, Ph.D., of the AMC Cancer Research Center, on a research consortium using the Cancer Information Service, recently funded by the National Cancer Institute.

- The Leadership Core applied for and received DOD approval for a no-cost one-year extension.

REPORTABLE OUTCOMES

At this time, the Leadership Core continues to provide integrative oversight and management of all aspects of the BCE to maximize the efficiency of its inter-coordinated organizational structure. The Core continues to develop, refine, and evaluate the overarching, unifying conceptual framework in its efforts to oversee and enhance the centralized quality control mechanism for designing, refining, and evaluating the theoretically-derived assessments and interventions. The Core remains active in the ongoing maintenance of the Training Program.

- Presentations(for abstracts see Appendix #16):

  Miller, S.M., Buzaglo, J.S., Bernabeo, E., Roussi, P., Daly, M.B., Pope-Mabe, M. Annual Meeting of the American Society of Preventive Oncology. Poster on: Decision making among high risk women undergoing breast/ovarian genetic testing. Bethesda, MD, February, 2006.

  Miller, S.M. Invited Speaker on Cognitive and emotional aspects of the response to cancer risk. Stress and Anxiety Research Society (STAR), University of Crete, Rethymnon, Crete, Greece. July, 2006.

  Miller, S.M. Invited Speaker on New Research Directions in Aging and Disparities: Cancer control in action. Sponsored by Case Western Comprehensive Cancer Center, Case Western Reserve University, Cleveland, OH September, 2006.

- Publications (for abstracts see Appendix #16):

Hurley, K., Miller, S.M., & Rubin, L.R. (2006). The individual facing genetic issues: Information processing, decision making, perception, and health-protective behaviors. In S.M. Miller, S. McDaniel, J. Rolland, & S. Feetham (Eds.), Individuals, families and the new era of genetics: Biopsychosocial perspectives. (pp. 274-319) New York: Norton Publications.

Miller, S.M., Fleisher, L., Roussi, P., Buzaglo, J.S., Schnoll, R.A., Slater, E., Raysor, S., & Popa-Mabe, M. (2005). Facilitating informed decision making about breast cancer risk and genetic counseling among women calling the NCI's Cancer Information Service. Journal of Health Communication, Special Issue on The National Cancer Institute's Cancer Information Service: A New Generation of Service and Research to the Nation,10, 119-136.

Miller, S.M., Daly, M.B., Sherman, K., Fleisher, L., Buzaglo, J.S., & Godwin, A. (2006). Psychosocial Processes in Genetic Risk Assessment for Breast Cancer. In S.M. Miller, S. McDaniel, J. Rolland, & S. Feetham (Eds.), Individuals, families and the new era of genetics: Biopsychosocial perspectives. New York: Norton Publications.

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Miller, S.M. & Wang, C. (in press). Psychological issues in genetic testing. In S.M. Miller, D.J. Bowen, R.T. Croyle & J. Rolland (Eds.), Handbook of behavioral science and cancer. Washington, D.C.: American Psychological Association.

Miller, S.M., Bowen, D., Croyle, R. & Rowland, J. (Eds.) (in press) Handbook of behavioral science and cancer. Washington, D.C.: American Psychological Association.

CONCLUSION

Members of the BCE continue to successfully assist all research teams accomplish their tasks during its second year. Our efforts have remained focused on the development of the necessary infrastructure between project staff and the other core facilities in order to facilitate synergistic research efforts and integrative findings across the multiple projects.

REFERENCES

N/A

DOD Progress Report
Communications Core

Suzanne M. Miller, Ph.D., Principal Investigator
Linda Fleisher, MPH, Core Director

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

The Communications Core has provided critical support and services for the research projects in the Behavioral Center of Excellence in Breast Cancer (BCE). The Communications Core builds on and extends the infrastructure, resources and expertise of the FCCC Behavioral Core to include state-of-the art communications theory and applications.

The Communications Core has two primary functions. The first, descriptive function consists of assessing information needs and culturally specific beliefs of populations targeted by the different Center projects. The second primary function of the Communications Core is to successfully translate this information into effective communication messages and strategies that meet the needs of the target population. To this end, the Communications Core conducts in-depth needs assessments of the target populations through focus groups for each individual research project; analyzes the information obtained; and assists in developing appropriate patient-tailored health communications.

Specifically, the aims of the Communications Core are:

Aim 1: To provide linkages to the FCCC Behavioral Core for assistance in evidence-based behavioral approaches and measures.

Aim 2: To expand the Behavioral Core resources to include communication theory and applications.

Aim 3: To facilitate the assessment of information needs of the target populations through focus groups.

Aim 4: To provide consultation in the development of interventions using behavioral, health education and communication principles and theories.

Aim 5: To provide formative evaluation services (e.g. implementation and analysis) to inform the development and pilot testing of interventions for specific populations.

By utilizing the Communications Core for all research projects an economy of scale is created with a synergistic impact that benefits and informs each of the projects as well as the entire Behavioral Center of Excellence.

These goals are achieved through a structured consultation and implementation process that includes an initial contact and needs assessment phase, a planning phase, and an implementation and follow-up phase. Throughout these phases, members of the Communications Core and members of the individual research projects have been in frequent contact to ensure that the objectives of the individual research projects are achieved.

BODY

The Communications Core over the course of the Center has worked closely with Investigators to develop assessment approaches (e.g. focus groups) to gather critical information to address specific needs of the target audiences, integrate communication theory into the interventions and provide consultation for all projects. The Communications Core has also developed a Resource Repository of literature and resources on communications, tailoring, cultural implications and literacy.

In year 5, the Core has focused on the final phases of intervention implementation, manuscript preparation and development and strengthening linkages to the FCCC Behavioral Research Core. The Communications Core has been successful in supporting each research project as specified in the Statement of Work. Over this past year, we have continued to expand the resource library, identify potential publications regarding the development of the interventions, assist in the development and refinement of project recruitment strategies. Underlying each of these accomplishments has been the Core's effort to integrate the Communications Core with the FCCC Behavioral Research Core.

KEY RESEARCH ACCOMPLISHMENTS

- Attend and participate in monthly Center meetings.

- Members of the Communications Core have continued to augment the library of the Behavioral Research Facility with articles from the communications literature. Additional resources on cultural issues have been added. This resource is made available to all members of the BCE, as well as the wider community of researchers at FCCC.

- The synergistic relationship between the Core and the FCCC Behavioral Research Core has resulted in an innovative, additional resource. In particular, the recruitment approaches and strategies developed by the Core have evolved into the FCCC BRCF's Recruitment Committee which will provide support for researchers interested in expanding participation among minorities and community organizations.

Further, project-specific accomplishments follow:

- **Project I.** In collaboration with project staff the Communications Core has initiated manuscript development on focus group results. The Core also has contributed to the refinement and improvement of the project's recruitment strategies. The Core helped to identify four recruitment sites within the community and form partnerships with these organizations and individuals. Moreover, the Communications Core utilized the FCCC Behavioral Research Core as a resource for evaluating and improving recruitment communication tools to be used in the refine recruitment efforts (e.g., reviewed recruitment flyers).

- **Project II.** All interventions have been reviewed and implemented. Discussions regarding manuscripts have been initiated.

- **Project III.** Members of the Communications Core have regularly met to develop an analysis plan for the focus group data.

- **Project IV.** The research team and members of the Communications Core have consulted and identified additional opportunities for recruitment.

REPORTABLE OUTCOMES

Other than the key research accomplishments detailed above there are no reportable outcomes.

CONCLUSION

Members of the Communications Core have successfully assisted all research teams accomplish their tasks during their fifth year. Our efforts have focused on finalizing assessment and materials and analysis of focus group data to inform study procedures, protocols and materials. The Core has provided ongoing feedback at the monthly meetings and provided strategies for recruitment. We have also continued to add to the BRCF library by identifying and including key health communication research articles.

REFERENCES

N/A

DOD Progress Report
Informatics Core

Suzanne M. Miller, Ph.D., Principal Investigator
Eric Ross, Ph.D., Core Director

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

The varied populations studied in this Behavioral Center of Excellence in Breast Cancer (BCE) and the complexity of the designs required the development of study-specific computer based tools to provide critical project management and coordination, and for the collection, validation, storage, retrieval and analysis of data. The projects contained in this BCE include: Understanding Breast Cancer Risk Assessment and Screening Behavior Among the Underserved, Cancer-A Teachable Moment Within the Family: From Concept to Community, Facilitating Re-entry Following Treatment for Primary Breast Cancer, and Impact of a Communication Skills versus a Supportive Therapy Intervention for Women with Metastatic Breast Cancer.

The objective of this core is to facilitate the research conducted in this BCE by providing (1) a central repository for all of the data included in the research, (2) data entry and validation services and (3) report generation and standard statistical programming services. Included in this core data repository are: a) socio-demographic data on study populations, b) clinical information, c) family history, d) genetic testing data, e) psycho-social data, f) health history data, g) quality of life data, h) cancer screening data, and i) diet data. Data from approximately 1000 subjects collected in four research projects will ultimately be stored in this information system.

The specific aims of the core are:

Aim 1: To provide computer-based tools that facilitate the entry, storage, manipulation and retrieval of the large quantities of data generated in the proposed research.

Aim 2: To ensure the accuracy of the data maintained in the database by developing human and software based data consistency and quality control systems.

Aim 3: To provide high-quality data entry services.

Aim 4: To organize and maintain the database to maximize accessibility, while maintaining strict confidentiality.

Aim 5: To provide statistical computing support.

Below, we specify the tasks to be accomplished in the context of these projects.

Task 1. Provide computer-based tools that facilitate the entry, storage, manipulation and retrieval of the large quantities of data generated in the proposed research.

a. In collaboration with the project investigators and research teams clearly define the specifications of the required information systems
b. Carefully design the needed database structures
c. Develop database tables
d. Design, and develop electronic data entry/retrieval systems
e. Test the electronic data entry/retrieval systems
f. Design and develop report and letter generation software

g. Test report and letter generation software
h. Review of applications by Project Investigators and research team members
i. Make modifications as needed.
j. Release software into production
k. Support and enhance software system software as needed

Task 2. Ensure the accuracy of the data maintained in the database by developing human and software based data consistency and quality control systems. Provide data entry and data validation services. Provide statistical computing support.

a. In collaboration with the project investigators and research teams design, develop and test data quality assurance systems
b. Conduct data entry and data validation
c. Provide statistical programming services

BODY

The details of the information system developed for the four research projects are described below.

Project I: Understanding Breast Cancer Risk Assessment and Screening Behavior among the Underserved

The overall goal of Project I is to identify and assess barriers and facilitators to participation in breast cancer risk assessment and adherence to breast cancer screening recommendations among African American women.

Core staff collaborated with project investigators and staff to refine and finalize the data flow and telephone data collection instruments. The relational database management system for this project is complete. Core staff used a case tool (PowerDesigner 6.1.0) to model the database, represent the physical organization of data in a graphic format, generate database creation and modification scripts, define referential integrity triggers and constraints, generate extended attributes, and generate a data dictionary. Core staff designed and developed a Computer Assisted Telephone Interview (CATI) system to meet the specific needs of this study. The application calculates each participant's estimated risk of developing breast cancer through an interface with a FORTRAN implementation of Mitchell Gail's algorithm. A graphical user interface (GUI) system for displaying and scheduling follow-up phone interviews was developed and is currently being used by project staff. Views of the database have been created and data dictionaries prepared to facilitate analyses by investigators and study biostatisticians. Additionally, core staff have produced descriptive statistics used in scientific and accrual reports and an Era of Hope presentation.

Project II: Project II: Cancer – A Teachable Moment within the Family: From Concept to Community

The goal of this study is to test the effectiveness of a tailored intervention to increase participation rates in a FCCC high-risk breast cancer program (i.e., FRAP). A secondary aim is to explore the effect of the intervention on breast cancer screening practices.

Core staff collaborated with project investigators and research staff to refine and finalize the data flow and hardcopy data collection instruments. The relational database management system for this project is complete. This system will maintain all of the information collected in this study including: health history, clinical, epidemiologic, socio-demographic, and psychosocial data. In addition, this database contains cancer and vital status data on relatives of individuals recruited into the study. The software system coordinates numerous tasks, including the scheduling of follow-up visits, and the distribution of mailed self-report questionnaires. This system generates multigenerational pedigrees from the union of family histories provided by two or more distinct study subjects in the same family. The family data can be updated from follow-up information to include deaths or new cancers reported for study subjects, previously listed family members, as well as new births. The system randomizes participants to study arm based on strata defined by the participant's MBSS score, her family history (of cancer) and date of last mammogram. Tailored and control scripts are automatically generated at time of randomization using Oracle Reports. Core staff also developed: a ticker/reminder system to notify appropriate staff when a 12-month follow-up phone survey is due; report generation software to produce printed materials (dependant upon study arm assignment) and accompanying cover letters; and database views that are used by project staff to display information about study participation. All software has undergone thorough testing. Additionally, core staff have generated descriptive statistics for usage in scientific and accrual reports and an Era of Hope presentation.

Project III: Facilitating Re-entry Following Treatment for Primary Breast Cancer

The primary objective of this study is to develop and evaluate a C-SHIP guided Cognitive-Affective Processing (CAP) intervention to facilitate psychosocial adjustment at re-entry, following adjuvant treatment for primary breast cancer. Core staff reviewed draft data collection instruments and project timelines. Project III is conducting focus groups to help refine the cognitive-affective intervention. Design, development, testing and deployment of the production database for the randomized trial will begin following the completion of the focus groups and finalization of the data collection instruments and study timelines.

Core staff collaborated with project investigators and research staff to refine and finalize the data flow and hardcopy data collection instruments for participant enrollment and the storage of data from the participant's baseline and follow-up

assessments. The application for this project has been completed and maintains all of the data collected in this study. All software has undergone thorough testing by demonstrating that each function is operational and performs according to specification. Core staff have created views of the database and prepared data dictionaries to facilitate analyses by investigators and study biostatisticians.

Project IV: Impact of a Communication Skills versus a Supportive Therapy Intervention for Women with Metastatic Breast Cancer

The goal of this study is to compare a cognitive-behavioral intervention (with a communication and support training focus) to a supportive therapy intervention, on the quality of life of women with metastatic breast cancer. A secondary aim is to explore moderating effects of individual dispositional factors and mediating effects of support-related variables on the impact of the intervention strategies.

The relational database management system for this project has been completed. This system maintains all of the information collected in this study and facilitates many aspects of data collection and patient tracking. Core staff collaborated with project investigators and research staff to refine and finalize the data flow and hardcopy data collection instruments. Core staff prepared data dictionaries. PowerDesigner was used to model the database, represent the physical organization of data in a graphic format, generate database creation and modification scripts, define referential integrity triggers and constraints, and generate a data dictionary. A system for the scheduling of follow-up visits and electronic screens displaying subjects due for follow-up was also developed. All software has undergone thorough testing by demonstrating that each function is operational and performs according to specification. Views of the database have been created and data dictionaries prepared to facilitate analyses by investigators and study biostatisticians using SAS and SPSS. Additionally, core staff have produced descriptive statistics used in scientific and accrual reports and an Era of Hope presentation.

KEY RESEARCH ACCOMPLISHMENTS

- Core staff attends and participates in scheduled Center meetings.

- Core staff collaborated with project investigators and research staff to refine the data flow and hardcopy data collection instruments for all four projects. Core staff developed data dictionaries based on study requirements and data collection instruments.

- Core personnel have designed and developed comprehensive information management systems to meet the specific needs of all four projects. These customized relational database systems have been implemented using a combination of tools including, Java/J2EE, Oracle Forms, Oracle Reports, FORTRAN and Oracle database engine software. The database and management structure facilitate efficient data capture and

manipulation, as well as control the exchange of information across the projects. All software has undergone thorough testing before release to the user community.

- Data quality assurance procedures have been implemented using software-based data entry checks as well as post-entry manual audits.

- Software for the scheduling of follow-up visits, and the distribution of mailed self-report questionnaires has been developed for Project II.

- Software was developed for all Projects to generate reports that allow tracking of study accrual and progress of individual study subjects.

- All FCCC computers used for storing the information were protected from inappropriate outside access by the FCCC firewall.

- Security measures for accessing data have been implemented. The first level controls access to the desktop computers and web-server. Fox Chase Cancer Center uses a Lightweight Directory Access protocol (LDAP) directory service, implementing a subset of the InteOrgperson/EduPerson V2.0 schema, to provide a robust, extensible, and well-controlled common authentication mechanism. The second level of username/password based security takes place at the database server and application interface level. Each user is assigned a unique Oracle username/password. Restrictions are applied to each user commensurate with their needs to access the data (roles) at the application level.

REPORTABLE OUTCOMES

None

CONCLUSION

This Core serves as a resource for the Center of Excellence as a whole and will maintain a valuable source of data for current and future studies. By centralizing these services into an Informatics Core, we are better able to manage and coordinate the collection, storage, and distribution of a large amount of highly valuable data. Subject to informed consent, the information contained in the data repository will be available to all investigators in the Center of Excellence. By providing access to the data to all participants, sharing technical capabilities and ensuring the quality of the data, this core will not only facilitated achievement of the aims of the individual projects, but also make possible exploratory analyses beyond the stated aims of the projects.

REFERENCES

N/A

DOD Progress Report
Blood Collection and BRCA1 and BRCA2 Mutation Testing through the Genetic Susceptibility-Testing Laboratory Core

Dr. Suzanne M. Miller, Ph.D., Principal Investigator
Andrew K. Godwin, Ph.D., Core Director

Psychosocial and Behavioral Medicine Program
Division of Population Science
Fox Chase Cancer Center

INTRODUCTION

The strongest known epidemiological risk factor for breast cancer is a positive family history and studies of breast and ovarian cancer patients and their relatives consistently find statistical evidence for involvement of autosomal dominant genes. Therefore, the identification of specific genes has long been the focus of efforts to identify women at high risk. A promising approach for reducing the high incidence and mortality associated with breast cancer lies in the early detection of women at high risk. These women, once identified, can be targeted for more aggressive preventative programs and tailored interventions to help cope with their increased risk of developing cancer. As a result of the cloning of the two most prominent breast-ovarian cancer susceptibility genes, *BRCA1* and *BRCA2*, it is now possible to screen women from high-risk families for germ-line mutations. This Core was created to support Project 2, "Cancer-A Teachable Moment Within the Family; From Concept to Community" and Project 3, "Facilitating Re-entry following Treatment for Primary Breast Cancer". Project 2 proposes to test the efficacy of a health communication message personalized to a set of demographic, clinical, and psychosocial factors and timed to capitalize on the heightened awareness of breast cancer risk attributed to the recent diagnosis in a first-degree relative (FDR). The purpose of the health communication message is to encourage that these at-risk women participate in the Family Risk Assessment Program at FCCC or the Network Hospitals in order to receive personalized breast cancer risk information provided to the participants. *BRCA1* and *BRCA2* mutation analysis is offered to those who have familial patterns of breast cancer indicative of a possible involvement of a disease-associated germline mutation. Similarly, Project 3 proposes to provide tailored communications. However, the communications are provided to breast cancer patients actively undergoing treatment. The communications are designed to enhance adjustment, quality of life, and adherence to recommended follow-up regimens during survivorship. Participants are extended an offer to participate in FRAP to receive familial risk information. Eligible participants, based again on family history of breast cancer, are offered *BRCA1* and *BRCA2* mutation analysis.

Specifically, the aims of the Core are as follows:

Aim 1: To collect and bank blood samples from women with breast cancer or unaffected women with a family history of breast cancer as part of Projects 2 and 3.

Aim 2: To evaluate constitutive DNA from individuals participating in the Projects 2 and 3 for mutations in BRCA1 and BRCA2.

We have an extensive history of collecting and banking biospecimens from women at an increased risk for breast and/or ovarian cancer at the Fox Chase Cancer Center. During the past year we collected and processed blood samples from hundreds of FRAP participants and have screened for germline mutations in *BRCA1* and *BRCA2*. We have improved our methods to identify germline mutations as well as to assess the impact of these mutations on cancer risk. To date, we have identified more than **500 (550)** *BRCA1* and/or *BRCA2* mutation carriers (including **69 (84)** unique deleterious mutations) using our EMD approach. The personnel and methodology are in place to handle and screen the BCE samples as they are obtained. We attend

the monthly BCE meetings to discuss recruitment and to up date the progress we have made in our genetic testing.

BODY

The strongest known epidemiologic risk factor for breast cancer is a positive family history and studies of breast and ovarian cancer patients and their relatives consistently find statistical evidence for involvement of autosomal dominant genes. Therefore, the identification of specific genes has long been the focus of efforts to identify women at high risk. A promising approach for reducing the high incidence and mortality associated with breast cancer lies in the early detection of women at high risk. These women, once identified, can be targeted for more aggressive preventative programs and tailored interventions to help cope with increased risk. As a result of the cloning of the two most prominent breast-ovarian cancer susceptibility genes, *BRCA1* and *BRCA2*, it is now possible to screen women from high-risk families for germ-line mutations. We developed this Core base on our previous experiences in effectively collecting thousands of blood samples from research participants with family histories of breast and/or ovarian cancer, and in screening for mutations in *BRCA1*, *BRCA2*, and other candidate breast cancer susceptibility genes. This Core supports Projects 2 and 3 (as well as the other Project in the BCE if the need arises), by providing a highly accurate and cost-effective means for testing eligible participants for mutations in the two most prominent breast cancer susceptibility genes, *BRCA1* and *BRCA2*.

KEY RESEARCH ACCOMPLISHMENTS

- Improved the ability to detect *BRCA1* and *BRCA2* mutations in genomic DNA.
- Reduced the cost of full *BRCA1* and *BRCA2* mutation analyses to a third of the cost of commercial testing without loss of sensitivity.
- Created *BRCA1* and *BRCA2* exon chips for detection of genomic rearrangements in these two genes.
- Included mutation detection technology for large deletions/insertions in *BRCA1*, an extension of PCR based mutation detection; included in our *BRCA1* and *BRCA2* full screen will be testing for the panel of 5 *BRCA1* deletions/insertions currently performed by the primary *BRCA1/BRCA2* clinical testing agent.
- Further reduced cost for *BRCA1* and *BRCA2* mutation analysis by enzyme mutation detection by performing our own DNA sequencing.
- Identified 56 (**68**) novel polymorphisms common to ethnic populations; identified 5 novel frameshift mutaitons, 4 (**2**) novel intronic variants, and 38 (**25**) novel variants of uncertain significance in our ethnic populations.

- Developed a PCR based method to evaluate RNA for splicing changes in those specimens where intronic alterations have been identified.

REPORTABLE OUTCOMES

- Abstracts

*=supported by DAMD17-01-1-0238 ("Tailored Communications to Enhance Adaptation Across the breast Cancer Spectrum")
**=Demonstrates refinement and application of our methods to detect germline mutations in high-risk individuals.

- **Presentations**

*S.L. Neuhausen, H.T. Lynch, B.L. Weber, J.E. Garber, M.B. Daly, **A.K. Godwin**, T. Wagner, K. Nathanson, J. Farnham, S.A. Narod, T.R. Rebbeck. Modification of *BRCA1*- and *BRCA2*-Associated Breast and Ovarian Cancer Risk by *RAD51*. Proceedings of American Association of Cancer Research, 44:574, 2003.

- **Publications**

Wagner Costalas J, Itzen M, Malick J, Babb JS, Bove B, **Godwin A.K., Daly MB. Communication of *BRCA1* and *BRCA2* results to at-risk relatives: A cancer risk assessment program's experience. American Journal of Medical Genetics, 119C:11-18, 2003.

CONCLUSION

The work that we have preformed during the first four (five) years of this application has served to improve our ability to detect mutations in the two prominent breast cancer susceptibility genes, *BRCA1* and *BRCA2*. We have published our mutation detection method and have shown that it is comparable if not superior to commercial methods at a significantly lower cost. We have also developed a method to detect large genomic rearrangements in *BRCA1* and *BRCA2* that elude detection when using PCR-based approaches to search for mutations. We are also developing in our testing regimen a PCR based method for detecting large insertions/deletions in *BRCA1*. Overall, we are in optimal position to appropriately analyze any and all BCE samples once they become available through Projects 2 and 3. Furthermore, we will be able to process more samples than originally proposed due to our technical improvements and ability to automate the method.

REFERENCES

None

DOD Progress Report, October 30, 2006
APPENDICES

Leadership Core

Appendix # 16 – Abstracts of Presentations and Publications related to the grant

Abstracts of Presentations and Publications Related to the Grant

Presentations:

Miller, S.M., Buzaglo, J.S., Bernabeo, E., Roussi, P., Daly, M.B., Pope-Mabe, M. Annual Meeting of the American Society of Preventive Oncology. Poster on: Decision making among high risk women undergoing breast/ovarian genetic testing. Bethesda, MD, February, 2006.

ABSTRACT:

We explored the impact of an enhanced counseling intervention among high-risk women undergoing BRCA1/2 genetic testing on decision making regarding breast and ovarian cancer risk-reduction options. We compared standard individualized genetic counseling enhanced by a "Cognitive-Affective Preparatory" counseling intervention (CAP) to a control group (standard counseling plus General Health Information). Enhanced counseling involved structured role-play. Women were helped to anticipate and plan for the disclosure of all possible testing outcomes. All participants (N=95) were asked to provide an audiotaped account of their thoughts and feelings about their familial cancer risk and their genetic testing decision. Guided by the Cognitive Social Health Information Processing (C-SHIP) model, transcripts of the audiotaped accounts were coded for the presence of discrete thought units, and cognitive-affective units. Analysis of variance showed that women receiving enhanced counseling expressed more cognitive-affective processing than women in control condition, as measured by the number of identifiable thought units and the frequency of discreet cognitive-affective units (p=.002). Women who received CAP more frequently expressed perceived risk (p=.036), health-related values and goals (p=.012), negative affect (p=.02), self-efficacy (p=.003), and action plans (p=.004), than women in the control condition. The results suggest that cognitive-affective preparation may facilitate the deeper processing of risk feedback. This unique dataset combines qualitative and quantitative approaches to the understanding of how individuals process complex risk-related decisions.

Miller, S.M. Invited Speaker on Cognitive and emotional aspects of the response to cancer risk. Stress and Anxiety Research Society (STAR), University of Crete, Rethymnon, Crete, Greece. July, 2006.

ABSTRACT:

Individuals are characterized by a relatively stable structure of cognitions and affects that are likely to become activated when encountering health-threatening situations. Typically, individuals are not aware of these cognitions and affects in threatening situations, particularly when the situation is unfamiliar. As such, it becomes difficult to self-manage their emotions, plans, and behaviors. Moreover, just as individuals differ in the ways they perceive, define, and experience daily stress, they also differ significantly in the ways they how individuals process health-related information and stress. The Cognitive-Social Health Information Processing (C-SHIP) model provides a unifying framework for understanding how individuals process information about cancer threats and prevention-control options. This model explores individuals' distinct processing profiles in relation to health-relevant perceptions/encodings, affects/emotions, expectancies and beliefs, health-relevant values and goals, and self-regulatory

strategies. The present discussion highlights the efficacy of this model in a number of cancer contexts, including genetic testing, screening/diagnosis, and patient adherence. In particular, a series of studies demonstrating the application of the C-SHIP model are provided. Topics include an ovarian cancer surveillance program for abnormal screening, facilitating patient adherence through framed health messages, and the development of enhanced counseling using cognitive-affective preparation. Future directions of and public health implications for cancer prevention and control research are discussed.

Miller, S.M. Invited Speaker on New Research Directions in Aging and Disparities: Cancer control in action. Sponsored by Case Western Comprehensive Cancer Center, Case Western Reserve University, Cleveland, OH September, 2006.

ABSTRACT:
Individuals are characterized by a relatively stable structure of cognitions and affects that are likely to become activated when encountering a health-threatening situation. Individuals are not necessarily aware of these cognitions and affects in threatening situations, particularly when the situation is unfamiliar. This makes it difficult to self-manage their emotions, as well as enact plans and behaviors. Individuals differ in how the perceive stress, how they define stress, how readily they find stress, and how they maintain and relive stress. Dependant upon how individuals deal with stress, they are likely to fall into one of two categories; high monitors, which refers to the extent to which individuals attend to, scan for, and amplify information about cancer threats, or low monitors, also referred to as blunters. Low monitors or blunters are more likely to ignore, be distracted from, and minimize information about cancer threats. The Monitor Blunter Style Scale (MBSS) was developed to identify high monitors and low monitors (blunters). The scale is psychometrically sound, and a useful tool for exploring interactions between individuals and medical feedback. Women at risk for ovarian cancer enrolled in a surveillance program. High monitors with abnormal screening results showed greater post-result increases in distress as compared to low monitors or blunters who received the same results. One year after false positive results, high monitors continued to report significantly higher levels of distress and anxiety than low monitors. The impact of an Enhanced Counseling intervention, designed to promote well-informed decision making for follow-up risk reduction for ovarian cancer, among high-risk women undergoing BRCA1/2 testing (N=77) was evaluated. Following standard genetic counseling, participants received either the enhanced counseling session, or a general health information (GHI) control session. The enhanced counseling interventions included structured role play, pre-living, and identification of likely choices and possible dilemmas. From baseline to post-testing feedback, women who received Enhanced Counseling displayed a greater reduction in intrusive ideation ($p<.05$), and a greater reduction in avoidant ideation ($p<.05$) compared to women who received Standard Counseling. Thus, the public health implications for cancer prevention and control are clear. Cancer communications need to assess and address patient cognitive-affective processing signatures in a systematic and preparatory fashion. It is likely that cancer communications will be most effective when they are targeted to socio-demographic and cultural factors and tailored to individual coping styles and developmental stage.

Publications:

Hurley, K., Miller, S.M., & Rubin, L.R. (2006). The individual facing genetic issues: Information processing, decision making, perception, and health-protective behaviors. In S.M. Miller, S. McDaniel, J. Rolland, & S. Feetham (Eds.), Individuals, families and the new era of genetics: Biopsychosocial perspectives. (pp. 274-319) New York: Norton Publications.

ABSTRACT:
Accumulating research has shown that people vary widely in their responses to genetic information, with key variables such as distress levels and perceived risk showing large individual differences. In order to capture the highly personal nature of genetic feedback information and the implications of this feedback for major decisions, life plans, and concepts of the self, the clinical descriptive approach—which captures the richness of individual experience— needs to be integrated with empirical methods that seek to establish lawful relations between constructs. The purpose of this chapter is to examine the nature of the information-processing task and to systematically delineate the psychological operations that underlie the individual processing of genetic information.

Miller, S.M., Fleisher, L., Roussi, P., Buzaglo, J.S., Schnoll, R.A., Slater, E., Raysor, S., & Popa-Mabe, M. (2005). Facilitating informed decision making about breast cancer risk and genetic counseling among women calling the NCI's Cancer Information Service. Journal of Health Communication, Special Issue on The National Cancer Institute's Cancer Information Service: A New Generation of Service and Research to the Nation,10, 119-136.

ABSTRACT:
Despite increased interest among the public in breast cancer genetic risk and genetic testing, there are limited services to help women make informed decisions about genetic testing. This study, conducted with female callers (N = 279) to the National Cancer Institute's (NCI's) Atlantic Region Cancer Information Service (CIS), developed and evaluated a theory-based, educational intervention designed to increase callers' understanding of the following: (a) the kinds of information required to determine inherited risk; (b) their own personal family history of cancer; and (c) the benefits and limitations of genetic testing. Callers requesting information about breast/ovarian cancer risk, risk assessment services, and genetic testing were randomized to either: (1) standard care or (2) an educational intervention. Results show that the educational intervention reduced intention to obtain genetic testing among women at average risk and increased intention among high-risk women at 6 months. In addition, high monitors, who typically attend to and seek information, demonstrated greater increases in knowledge and perceived risk over the 6-month interval than low monitors, who typically are distracted from information. These findings suggest that theoretically designed interventions can be effective in helping women understand their cancer risk and appropriate risk assessment options and can be implemented successfully within a service program like the CIS.

Miller, S.M., Daly, M.B., Sherman, K., Fleisher, L., Buzaglo, J.S., & Godwin, A. (2006). Psychosocial Processes in Genetic Risk Assessment for Breast Cancer. In S.M. Miller, S. McDaniel, J. Rolland, & S. Feetham (Eds.), Individuals, families and the new era of genetics: Biopsychosocial perspectives. New York: Norton Publications.

ABSTRACT:
To comprehensively address the needs of women and their spouses or partners and extended family at increased risk, psychosocial researchers and practitioners need to have a foundational knowledge of breast cancer genetics and prevention, including available risk reduction options. It is also important for them to understand women's knowledge about their risk, as well as the psychological sequelae that result from the complex decisions and options faced by at-risk individuals. This chapter provides an overview of the current state of the science in breast cancer genetics and available approaches to risk assessment and management, with an emphasis on the psychosocial impact of this emerging technology on women and their families. It concludes with recommendations to improve current research and practice in this area.

ABSTRACT:

Miller, S.M., McDaniel, S., Rolland, J., & Feetham, S. (Eds.) (2006) Individuals, families and the new era of genetics: Biopsychosocial perspectives. New York: Norton Publications.

ABSTRACT:

Practitioners and scholars representing a variety of fields assess the impact of genetic knowledge and emerging genetic options on individuals and family life. These assessments consider perspectives ranging from the theoretical to the clinical to the ethical and legal. Across all of the chapters, the authors bring theoretical, methodological, and clinical issues to bear as they address such key issues as information processing, risk assessment, informed decision making, quality of life, behavior change, and family communication. From within a unified framework of individual and family dynamics, this book discusses the impact on the individual and the family of information regarding heritable behavioral traits and organic diseases, as well as decision making in light of genomic information, the design and evaluation of psychosocial interventions for those with genetic susceptibility or inherited conditions, and psychosocial support and guidance for family members who live with the expectation of illness or loss due to heritable predispositions or conditions. These general concepts of psychological patterns and social relations are also applied to specific genetically heritable conditions such as Huntington disease, cystic fibrosis, cancer, diabetes, cardiovascular disease, and schizophrenia, as well as to reproductive issues. Throughout, the authors weave together the conceptual, empirical, and practical implications in a way that will directly contribute to the research and clinical work of health and mental health professionals. Ethical, legal, and policy issues pertaining to genetic testing and screening are also discussed.

Miller, S.M. & Wang, C. (in press). Psychological issues in genetic testing. In S.M. Miller, D.J. Bowen, R.T. Croyle & J. Rolland (Eds.), Handbook of behavioral science and cancer. Washington, D.C.: American Psychological Association.

ABSTRACT:
This chapter provides an overview of the psychological issues involved in genetic testing for hereditary cancer syndromes. These issues are organized around the evidence base in the following areas: 1) the psychosocial and background factors that predict genetic testing uptake; 2) the impact of genetic risk feedback on psychological responses, preventive and management decisions, and health behaviors; and 3) future directions, focusing on the design and evaluation of psychosocial interventions to facilitate information processing, decision making and psychological and behavioral responses to genetic testing.

Miller, S.M., Bowen, D., Croyle, R. & Rowland, J. (Eds.) (in press) Handbook of behavioral science and cancer. Washington, D.C.: American Psychological Association.

ABSTRACT:
This volume integrates basic and applied research in the behavioral and social sciences with biomedical advances in our understanding of the carcinogenic process. The handbook brings together senior scientists to provide a comprehensive and unifying overview of the key areas of research in this area, with a conceptual and methodologic focus on incorporating tailored assessments of decision making, quality of life, and adherence into cancer prevention and control interventions, with a view to significantly reducing the burden of cancer. Emerging areas that are reviewed include innovative approaches to primary prevention, genetic risk assessment and management, the survivorship experience, and the utilization of new media technologies for effective cancer communication. In addition to these new research avenues, progress in the more traditional areas of cancer prevention and control research, notably cancer screening and treatment, are systematically addressed.